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United States Department of Agriculture

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HACCP IMPLEMENTATION MEETING)

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UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:)
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HACCP IMPLEMENTATION MEETING)

Federal Hall
Washington Plaza Hotel
10 Thomas Circle, N.W.
Washington, D.C.

Tuesday,
December 16, 1997

The above-entitled matter commenced, pursuant to notice, at 8:06 a.m.

APPEARANCES:

Panelists:

CATHERINE WOTEKI
THOMAS BILLY
PATRICIA STOLFA
MARK MINA
BILL SMITH
CHARLIE GIOGLIO
CAROL SEYMOUR

C O N T E N T S

P R O C E E D I N G S

MS. WOTEKI: Good morning, everyone. I am Cathy Woteki, Under Secretary for Food Safety at the Department of Agriculture. I would like to welcome you to this first of what are going to be four public meetings about HACCP implementation.

This is certainly I think an interesting time for us. Certainly HACCP, when it is implemented in January, is going to be a really landmark event. Since that date in January is very rapidly approaching, we are having this series of four meetings to discuss HACCP implementation.

I have had the opportunity over the four months that I have been in this job to travel around the country and meet with a lot of groups, industry groups, consumer groups, scientific organizations that are interested in research on food safety and new technologies to improve food safety.

In all of those meetings that I have had, I have always emphasized that our number one priority, my number one priority, the Agency's number one priority, is HACCP implementation. That, though, by itself is not our entire food safety strategy, but it certainly provides us with the underlying structure for a very sound strategy. As we implement HACCP, I believe it is going to provide the foundation for further improvements, as well as over time a

reduction in pathogens within the food supply.

HACCP is also a very important element of the President's food safety initiative. The initiative encourages the use of HACCP principles throughout the food industry, not just in meat and poultry or seafood inspection, as a means of identifying and controlling hazards that could threaten the safety of food and as a means of focusing on the greatest food safety risks.

I am very pleased with the progress that the Food Safety and Inspection Service has made to prepare for the first implementation date for HACCP. I have also taken the opportunity to look at the training tapes that all of our inspectors have been viewing as they have been undergoing the HACCP training. I found them to be very informative, to be very done, and I believe that our inspectors are going to be ready and well prepared for HACCP implementation come January.

I am also very pleased with the job that our excellent staff at FSIS has done to help industry to prepare for implementation. As you know, from the very beginning of the process of developing pathogen reduction in HACCP rules, FSIS has held countless public meetings to receive input, advice, recommendations, thoughts from our various constituencies and to provide assistance to plants required to implement the provisions of this rule.

I strongly support this open and participatory process, and I believe all of the time and work invested really do make a difference. I look forward to what I know is going to be successful implementation of HACCP.

I am planning to spend almost the entire day here. Unfortunately, I am going to have to leave for about an hour and a half to meet with the Secretary late this morning, but, as I said, I do intend to be here throughout the day except for that one interruption.

I would like at this point to introduce Mr. Tom Billy, the FSIS Administrator, who also has some opening remarks.

MR. BILLY: Thank you very much, and good morning to all of you. We very much appreciate your being here. This is a very important point in time in terms of the anticipated initial deadline for HACCP implementation in the largest plants.

We can tell by the number of people here that you are keenly interested in the dialogue that we are going to have today. We plan to get into various areas in some depth to give you a chance to both understand our thinking and approach to HACCP implementation, as well as to answer questions or concerns that you have.

This will be the first of a series of meetings that we intend to hold around the country. If any of you or

your colleagues wish to attend those other meetings, you are encouraged to do so. Often when you hear another question asked in a different way it can give you further insight, so we encourage full participation as we hold these public meetings.

We have a very full agenda. We are going to follow that agenda pretty closely. You will note that in most instances we will present a brief set of prepared remarks to set the stage. We plan to keep those remarks short and provide ample time for you to ask questions.

Those of you who have participated in these meetings before are familiar with the process we are going to follow, but I am going to repeat it for those of you that are not or to remind those of you who have been through it.

As we complete our presentations and you wish to speak, it is very important that you first get recognized by me. You do that by standing up at the mike or holding up your name tag if you have a name tag, and I will recognize you in sort of a first come/first served sequence.

I will permit a reasonable amount of exchange if it is to the same point. In other words, if someone wants to ask another question about the same point or add something, then we can go out of sequence in the sense of making sure we have pinned down the right understanding on a particular issue. We will play that by ear and see how it

works.

Those of you on the far end of the table, I have already made one trip down there because it is so far. You really need to get your placards up so we can see them and get your name down. Keep an eye on me in that regard.

We are going to use visual material. You may want to move around. If you do, you are welcome to do that. The most important thing is that you come away from this meeting with your questions answered.

We also have put out on the table a lot of materials. If you have not stopped by the table next to the registration desk, I encourage you to do so. Included there are directives, a series of directives that we will be using to implement HACCP, as well as a series of white papers that describe various documents in the works or other policy positions that we plan to follow in terms of implementing HACCP come January 26.

I plan to save the introductions of the presenters to when it is their turn in the barrow. However, there is one person I wanted to introduce in particular, someone that is relatively new to the Office of Food Safety, Karen Wilcox. Karen is the Deputy Under Secretary for Food Safety. She, too, plans to sit in during this session.

I am sure that when we have our breaks or whatever you will have a chance to talk to her and to get to know

her. She comes to us with an extensive background in the food safety regulatory area, and we very much appreciate having her here as part of the Food Safety team in USDA.

Are there any general questions or points that anyone would like to make at this stage before we get into the program?

(No response.)

MR. BILLY: All right. Very good. Then we would like to move on. The first item on the technical part of the agenda is HACCP/pathogen reduction implementation. Pat Stolfa will be the presenter, as well as the person to handle most of the questions, although we do have a team up here that will join in as appropriate.

Pat is the Deputy Assistant Administrator for Regulations and Inspection under the Office of Policy, Program Development and Evaluation. She is very, very familiar with the technical policy aspects of the HACCP regulations, so you should take advantage of this to ask any questions that you might have in that arena.

Pat?

MS. STOLFA: Thank you, Tom.

Good morning, and thank all of you for being here today for the first of our series of implementation meetings of talking about particularly the HACCP requirements of the final regulation we published in July of 1996.

I think it is with a sense of excitement and achievement, and I hope many people in this room share that, that we look forward to the first implementation deadline on January 26, 1998. We are finally at the point when for the largest establishments in the country all of the regulatory features of the HACCP/pathogen reduction final rule will be in place, and we think that that is an important accomplishment and one in which many, many people have shared.

Within the past month, we have issued our implementing directives, primarily the 5000.1, which looks like this and which I hope you picked up off the table, and the 5400.5. These are important and I think different directives for us, directives that are a break with the kind of directives we have done in the past as in fact the regulation is.

When we began the process of constructing these directives, we knew we had a formidable challenge ahead of us because there was so much and such fundamental change occurring both within the Agency and the regulated industry and in the relationship between the two of us.

We had certain objectives in mind, and those are listed for you to review. We wanted to have directives which took advantage of the new FSIS organization, directives that could be administered in 18 district

offices, that would take advantage of the new resources of the Technical Services Center and that would fully utilize the expanded capacity of our three technical support labs.

We wanted to have directives that would enhance the regulatory oversight model that we began implementing with sanitation standard operating procedures. We wanted to have directives which would reinforce and accelerate Agency progress toward having a system that was flexible, that permitted industry flexibility without compromising food safety performance standards.

Perhaps my primary objective was to make very certain that we had directives that were very true to the final regulation. We did not want to have any surprises in these directives. Every single requirement of that final regulation needed to be included in the implementing directives, and there are not going to be any requirements that are not in the final regulation. I hope that as you are looking at the directives you will come to some conclusions about whether or not we have succeeded in that regard.

To set the context of the implementing instructions to inspection personnel, I want to remind you of the regulatory model. That is what we have up here now. The regulatory model is one in which the previous blurring of the line between industry responsibilities and Agency

responsibilities is hopefully slowly but surely going away.

We believe under this regulatory model that it is the responsibility of the regulated industry to comply with meat and poultry inspection laws and regulations. Under this regulatory oversight model, industry assumes full responsibility for production decisions and execution. FSIS, on the other hand, is responsible and accountable to the consuming public for making sure that industry actions comply with those laws and regulations.

As the regulatory oversight model depicts, the first and fundamental tool that FSIS will use in making these determinations about regulatory compliance is called verification. As it is articulated in the final rule, FSIS will use a variety of verification techniques.

The overall purpose of FSIS verification is in order for inspection program personnel to make determinations about whether or not the industry is in compliance or not in compliance with regulatory requirements.

For purposes of HACCP and other features of the final rule also, we believe that verification activities can be divided into two broad categories. We call them Basic Verification and Other Verification. You can see that imaginative names are not something we go in for, so this is basic. If it is not basic, it is other.

The concept of basic non-compliance determinations was used when we implemented the sanitation SOP requirements. It is the idea that certain key features of a written document, whether that document is a written sanitation SOP or whether it is a HACCP plan. There are certain key features that can be relative easily determined to be present or absent.

We looked at the regulatory requirements of Part 417, and we came to believe that there were certain features of a company's HACCP plan which could be considered basic. That is, we could look at the HACCP plan, and without too much trouble we could tell whether or not they were there and whether or not in this most basic sense the regulatory requirement had been satisfied.

You will remember that when we were implementing sanitation SOPs, I think there were five regulatory requirements that needed to be present in the written sanitation SOP at the time of initial implementation. In the case of HACCP plans, the list is longer and is more complex, but the concept of basic compliance and making that judgement with relative ease is the same.

To make it easier for inspection system personnel to look for all the features of a HACCP plan which are required in Part 417, we prepared Form 5000-1, the HACCP basic compliance checklist. It is an attachment to this

implementing directive.

This is a two sided form, so Ron is just going to give you a quick glance at both pages. You are better off looking at the version that is a little closer to your eyes probably. Note that the form itself looks a lot like Part 417, and in fact the implementing directive itself is fully supported by references to Part 417.

The only change we have made to go from the regulations to the directive and the form is a little bit of grouping in order to make the form easier to use. If you just went right down the regulations, you would be going back and forth in a couple of instances. We just put things together in what we felt were logical groups, and that is how we got this form.

Note also in the case of HACCP plans the list of key features which need to be present is both more complex and more lengthy than the five features that had to be present in the written sanitation SOP. However, I do think that there are many features that inspectors would be looking for as a part of the basic compliance checklist which are in fact very simple. Is the form signed? Is there a flow diagram included? Are there monitoring procedures and critical limits at critical control points?

These are not difficult determinations to make. The concept of basic compliance I think is very familiar to

people in the industry and one that I believe we have a considerable chance of handling with a good deal of ease at the early stages of implementation.

The second broad category of verification which will be used to determine compliance with the regulatory requirements in Part 417 is that one we call Other. In several respects, making other non-compliance determinations is different from basic.

In the first place, it focuses on the adequacy of the HACCP system in operation, not whether or not something is included in the plan. Focusing on the adequacy of a system in operation is in and of itself a more complex proposition than just looking at something and deciding if all the parts are there.

In addition, in order to come to judgements about the adequacy of a system in operation, we often need more information, more technical information, information that has to be gathered from a variety of sources, and so it might take more time to come to a conclusion about the adequacy of a system in operation.

We did not think a checklist was possible in the case of other non-compliance determinations, so instead of a checklist we have two new PBIS procedures which will be used.

The first is again imaginatively called Procedure

01. It focuses on one aspect of a HACCP system in operation such as monitoring or verification or corrective actions. It puts a spotlight in effect on that particular feature, and inspectors will be collecting information on which to make a judgement about whether or not the regulatory requirements for that particular feature of a HACCP system are being met.

Now, in gathering the information to make those determinations, inspection program personnel may use various techniques. They may make observations about what is going on and whether what is going on conforms to what is in the HACCP plan. They may review records. They may take samples. They may perform a hands on procedure like taking a temperature.

All of these data will be assembled in order to come to a decision or come to a conclusion about whether or not there is compliance or non-compliance with the regulatory requirements for this particular feature of a HACCP system. That then is Procedure 01.

The second procedure used to make these other non-compliance determinations takes a comprehensive look at the HACCP system in operation. It does so by having inspection personnel follow a product through the entire process from beginning to end.

As the product is followed, inspection personnel

will observe how the HACCP system is working, whether or not again the HACCP system conforms to the HACCP plan, whether or not appropriate actions are taken when deviations from critical limits are encountered, whether or not other regulatory requirements are being met as a product moves from beginning to end in the system.

The later presentations this morning, particularly Bill Smith's, will explain about exactly how this will work, but these are the basic concepts that are embodied in this directive that we will be using to make determinations about whether or not plants are meeting regulatory requirements that are contained in Part 417.

I have one other topic to address, and that is the reasons for and content of a series of policy notices on HACCP implementation issues, the first of which appeared in the Federal Register on November 28, 1997.

In the past several months, senior Agency officials have been receiving informal information about how large establishments were planning to meet the regulatory requirements of Part 417. Some of that information was worrisome because it appeared that there may be misunderstandings which could lead to a difficult early implementation period. We do not want to have a difficult early implementation period, particularly not with a group of establishments that we believe are most knowledgeable

about HACCP.

We decided to go forward with a series of policy notices which might help clarify matters on which the preamble to the final rule had either not been entirely complete or was not up to date or apparently did not communicate as well as we might have hoped it would. Because these are policy notices, they cannot and do not add to regulatory requirements already in place.

The one that has been published about zero tolerance is designed to clarify that the Agency views its existing zero tolerance regulatory requirements for both livestock and poultry as food safety performance standards. This means that in establishing HACCP plans is our expectation that visible fecal contamination would be identified in a hazard analysis as a food safety hazard and that, therefore, there would be one or more critical control points within specific critical limits and monitoring frequencies which would be designed to eliminate contamination with visible fecal material.

The policy notice also signals FSIS intent to continue its current verification activities regarding the zero tolerance standard. This means we will continue to verify that establishments meet this food safety standard at the points in the process and with the frequencies we presently use.

Among the documents available at the registration table is one issue paper entitled Next Steps on Zero Tolerance. It is a sort of preview of what might happen over the next several months relative to this issue. In it we indicate that perhaps the best way to look at zero tolerance is as a part of postmortem inspection.

The Government role in postmortem inspection has not substantially changed by the mere fact of implementing HACCP in large establishments. As most of you know, we are considering what ought to be the Government role in postmortem inspection through the HACCP inspection models project, and that project has not come to fruition yet.

We are willing to consider, however, whether implementation of HACCP in large establishments itself yields data which would justify a change in either the frequency with which such verification checks are performed or the point at which it is appropriate to perform that. Once HACCP implementation has settled in these establishments, we will undertake specific data collection and a review process to help us answer this particular question.

In the nearer term, we are advising the implementing directive for poultry zero tolerance and creating a companion directive for livestock establishments to make it clear that in establishments that have

implemented HACCP the consequences of failing verifications for this food safety standard will be integrated and consistent with any other type of HACCP procedure.

We have two other policy notices presently in the works. They are the subject of one other paper, which is available at the registration table. That paper is an issue paper that is talking about the contents of HACCP plans and in particular Federal Register notices addressing Part 417 requirements for the content of HACCP plans.

One aspect of this issue is something of a surprise to us. We had heard that some industry members thought that they could comply with one or more provisions of 417.2 by referring to good manufacturing practices or establishment actions in accordance with good manufacturing practices rather than by explicitly stating critical control points, critical limits, monitoring and verification procedures and corrective actions.

This is not the case. Part 417 requires that whenever a hazard analysis reveals a food safety hazard which is reasonably likely to occur, a HACCP plan has to have critical control points and all of the rest that goes with critical control points to make them effective -- critical limits, monitoring procedures, monitoring frequencies, etc. We thought it might be useful for us to be very explicit about the requirements of 417 particularly

relative to good manufacturing practices.

The other worrisome information that came to us regarding HACCP plans being developed in large plants was that many would consist of a single critical control point. We are not prepared to say that you cannot have a HACCP plan that meets regulatory requirements and has only one critical control point.

We are, however, prepared to say that we anticipate that in order to operate in accordance with Part 417 on a continuing basis, many establishments will find that multiple CCPs serve them better than a single CCP. Multiple CCPs could reduce a company's exposure to the need for production disrupting corrective actions that affect large amounts of product.

As you take into account how large you might want to have your lots be, I would suggest that the question of multiple CCPs should be in the front of your mind as you consider what would be the consequences of a failure in a plan that has only a single CCP.

As we hear of other issues, and we hear of them from time to time -- we might even hear of some today -- on which we believe further clarification might be helpful, we will consider other policy notices. They appear occasionally and not according to any particular schedule. If things come up on which it appears to us it would be

advantageous for us to be clearer about our expectations, you may see more of these.

That is all for me. Thank you for your attention.

MR. BILLY: Thank you very much, Pat.

I assume that some of you have questions about what Pat has just presented. Make sure that you write them down so you do not forget them. When we get to the question and answer period, we will work our way through the questions that you have.

Does anyone have just a very general question of clarification of something Pat said just so you have it clear and you can prepare the question that you might have?

Katie?

MS. HANIGAN: Hi, Pat. Katie Hanigan with Farmland Foods. I have a question under your GNP versus CCPs.

Where we have written operating procedures for slaughtering animals which include the proper way to sanitarily dress a carcass, to gut the carcass out, etc., are you saying those cannot be written in operating procedures? Those must be CCPs?

MS. STOLFA: No, I am not saying that. I am saying that if a food safety hazard is identified, we expect there to be in the HACCP plan one or more critical control points that will be used to prevent, eliminate or reduce the

food safety hazard that you have identified.

They can certainly supplement. Those CCPs that are required to be in the HACCP plan can be supplemented by good manufacturing practices, company procedures, but if there is a food safety hazard identified, Part 417 clearly requires one or more CCPs to address it.

MS. HANIGAN: Can I ask more for clarification? For my own clarification, though, I guess I am still vague on it.

If you are going to gut 10,000 animals in the course of a week, you know, you have the potential maybe to have one carcass that you would need to take some type of corrective action on if it was inappropriately dressed.

I would have handled that under a standard operating procedure with corrective action. In that scenario would you be thinking that would be a CCP because you have the potential?

MS. STOLFA: Does the hazard analysis identify a food safety hazard reasonably likely to occur which you are attempting to control at that point?

MS. HANIGAN: Not if it's done correctly. Not if the animal is correctly eviscerated, etc.

MS. STOLFA: The judgement starts with the hazard analysis. Once there is a food safety hazard that is identified, you need to select one or more critical control

points at which you intend to control that food safety hazard and for each of those critical control points you need to have critical limits, monitoring procedures, frequencies, etc.

We are not saying and we would not want to imply that those cannot be supplemented by good manufacturing practices which do not have to rise to the level of a critical control point. If you have a food safety hazard identified, you have to have a critical control point someplace.

MR. BILLY: Okay. Dane?

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association. They wouldn't let me have a name tag because they did not want me to say anything.

MR. BILLY: You foiled us again.

MR. BERNARD: Foiled again.

Pat, I was probably not listening close enough, but you said something about the consequences of failure, and I think it was when you were discussing the zero tolerance issue. Could I get a clarification on what that was? I was not following the context of that.

MS. STOLFA: I was talking about our pending revision of the existing directive on performing zero tolerance checks in poultry slaughter establishments.

What I was saying is that we are making a revision

of that directive so that for establishments that have implemented HACCP, the consequences of failing those checks will be integrated and be similar to other HACCP procedures rather than the procedures that are now in place in all establishments and will remain in place in the establishments that are not implementing HACCP.

It is just a matter of making an appropriate distinction that recognizes that with the implementation of HACCP, failures have different consequences.

MR. BILLY: Rosemary?

MS. MUCKLOW: I have that general question that you were asking for, and that is that as I look at the form, HACCP Systems Basic Compliance Checklist, every question in there is a negative question. The form is either wrongly titled or the questions are wrongly titled because this is a HACCP systems basic non-compliance checklist.

I am disappointed because I think there should be an opportunity in each block to say that the standard has been met. There is an opportunity for a yes answer that means that the company is in compliance.

Everything in this form is negative, and I just think that is a very unfortunate way to begin a major, major change in an inspection program. That is obviously a policy decision on the part of the Agency. I would hope that we could begin the new day in January with a more positive,

cooperative approach and that there is a chance to say yes, this is being met. This is all extraordinarily negative.

MS. STOLFA: We did that deliberately, Rosemary. One of the things that troubled people a lot and continues to give people trouble is the notion that we are not approving HACCP plans. We are basically hoping to not have any checks on the forms. A form reflective of compliance does not have any non-compliances indicated.

As a matter of disciplining ourselves and helping people to remember that we are not in the business of approving things, as long as people are meeting regulatory requirements that is fine. As I say, we did that very deliberately to help us with a change in a mind set.

MS. MUCKLOW: Just as a follow up, when this gets out to the field we are talking again about the paradigm shift and of changing people's behavior and attitudes. If I really thought we would be successful with that on January 26, I would not be as concerned about the negative bias.

MR. BILLY: Rosemary, perhaps when you get a chance you could loan me your crystal ball because you seem to be able to foretell the future better than some of the rest of us.

MS. MUCKLOW: I would be glad to. Come sit at my desk.

MR. BILLY: I would like to move on now to the next presentation. To introduce the next speaker, I would like to call on Dr. Mark Mina.

Mark was recently appointed as the Deputy Administrator for Field Operations. In that role he carries out a very important set of responsibilities in terms of seeing through this transition to a HACCP based inspection system. Mark has a wealth of experience both in the field and headquarters. He brings an awful lot to this position.

Mark?

DR. MINA: Thank you, Tom. It is a pleasure to be here this morning and to see this large turnout turn out for the HACCP implementation that everyone here in this room and maybe outside the room takes very seriously. We do take it extremely seriously.

We are looking forward to the challenge of implementing a major, major change; not only the technical change, but I think culturally we are moving into a completely different direction both for the regulated industry and for our inspectors. That will continue to be a challenge for years to come.

January 26 is the beginning of the implementation of this major change. As you know, we have at least a three year schedule for implementing HACCP in all the plants starting with the large plants January 26. We take this

responsibility extremely seriously.

Let me tell you that we are ready for the implementation on January 26. We did a lot of things to prepare our work force. They will receive an eight day training that Bill Smith will talk about in great detail later on. It is not a one day training or a two day training or three days. It is an eight day training, and it is well designed to make sure that the inspector understands what we expect him to do on January 26.

I would like to make my comments very brief. I will be here also all day long, more importantly listening to your concerns and trying to address them. At this point, and we will continue this process. As Tom indicated earlier, we are planning four meetings across the country. This is for the first round.

The bigger round starts next year I think for the larger number of plants, and that is a major, major challenge for us to train roughly 3,000 inspectors in 3,000 plants. This is relatively the easier step in the process, and I am very confident that we are going to be very successful in implementing HACCP.

An indication is our implementation of SSOPs. There was a lot of apprehension prior to the SSOP implementation. We had several public meetings similar to the one we are having here today. I think it is extremely

important for us to communicate, continue to communicate, continue to respond to your questions and concerns and clarify maybe some of the misunderstandings. I am sure there are quite a few of them that we will hear about today.

With those brief remarks, I would like to introduce Bill Smith. He is the Acting Assistant Deputy Administrator for Field Operations, and he will talk about the verification process for HACCP and the passage of reduction regulations. He has also another piece. He will talk about training. Instead of introducing him twice, I will introduce him just once and have him cover both topics.

MR. SMITH: Thank you, Mark.

We would like to do a flip-flop here and have the training discussed first, and then we will talk about Agency verification.

We have begun our training effort. We are training 1,700 people for this first go round, 1,100 inspection personnel and then the balance would be our front line supervisors and compliance officers. As of last week we have trained approximately 600 people, so we feel we are well on our way to accomplishing our training and will meet the goal of January 26.

I have asked two individuals to help put on this training package. First would be Dr. Barbara Masters. She has been doing a lot of our point work and is our technical

expert on HACCP and HACCP implementation at the Technical Center. We have asked Dr. Ilene Arnold, who is a Circuit Supervisor in Philadelphia and one of our most experienced facilitators, to lead you through our training process. I will turn that over to them now.

DR. ARNOLD: It is my pleasure to be here today to speak to you not only from the point of view of a facilitator, but also as a field person. I am going to be talking to you about the HACCP technical training program.

To begin with, I just want to talk a little bit about the delivery strategies. Just as in the pre-HACCP SSOPs and cultural change training, like last year this training is also going to be just in time. The training sites that we are using are close to the work site of the large plants where the HACCP will be implemented on January 26, 1998.

The program, just as the program last year for the SSOPs and cultural change training, is video based. We have quite a number of very well produced videos that we are showing to the field personnel as we facilitate. The training is facilitator delivered, and for those of us who are not familiar with that term as a facilitator we basically help to move things along. We enter in discussions.

We help the participants with workshops and

basically help get the message across so that everyone that participates in the training program really has a good understanding by the time that they leave the training what they are supposed to be doing.

The facilitators function nationally with the new district structure. With SSOPs and the cultural training, we were kind of like in our regions, but now that we have gone to districts all the facilitators function nationally, which means that if we need facilitators in one area because there is more large establishments, then the facilitators will go there to help.

Currently in the State of Pennsylvania we have three sessions going on at one time utilizing six of the facilitator teams. We have a total of eight in Pennsylvania. We are using the concept of as large a group as possible, usually between 20 and 30 people, at these sessions. The sessions that I currently am involved in have 20 people in them and quite a large range of different people in those sessions. I will be talking about that in a little bit.

The delivery period for this large plant implementation will be December 1, so we already started -- there has already been one two week training session that has taken place -- through January 24, 1998. We will not be having sessions during Christmas and New Years week because

of the holidays and the fact that the training is two four day sessions. The very small and small plant implementation schedules are going to be announced at another time.

If we look at the immediate focus for the training, it is the employees, of course, in the field and the supervisors assigned to the large plants plus the circuit supervisors, the district office managers, compliance officers, which also include the compliance supervisors, and local union presidents.

Currently at the session that I just facilitated we had a district manager, we had the deputy district manager, we had compliance officers, circuit supervisors and a number of field personnel, so there is quite a variety of people that are in the training sessions.

The program, as already has been stated, consists of 11 modules, and they are delivered over a two week period, four days of training over each week for a total of eight days. There has been ample amount of time to go over the material each day to make sure that we reinforce as we go along that the participants are getting the key points in each module.

Now, I am going to just briefly discuss what each module contains just to give you an idea of what the training has in it. In the first module is the overview of FSIS' food safety goals and strategies. Basically the

purpose of this first module is to set the stage for the training program by presenting a concise, focused, big picture of FSIS' philosophy and operations.

That program basically is we are watching the video, and then we discuss some key points in the video, just as it says, to get a focus on what the big picture is of what FSIS' food safety goals and strategies are.

In the next module we talk about the HACCP overview and principles. The purpose of this module is just to kind of get the participants' feet wet. It is to introduce at a very basic level the principles and applications of HACCP. In this module, we discuss the seven principles of HACCP, and the participants get to view a video about HACCP and how HACCP systems work.

This is just a very basic module, and it is kind of the first thing that participants get to introduce them to what HACCP actually is and what the concepts are.

In the next module, Module 3, we discuss steps in the development of the HACCP system and the relationship of HACCP, a company's good manufacturing practices and the sanitation standard operating procedures.

Now, the purpose of this module is to provide a working knowledge of HACCP systems development and the relationship of a company's general manufacturing procedures and the sanitation standard operating procedures. It is

also to help impart understanding of the variety of ways that the industry might approach regulatory compliance.

This module is included so that the participants can get in an idea of how does a company go about developing a HACCP plan. During this module we talk about how do they identify CCPs and critical control limits, what do they do as far as establishing monitoring procedures, verification procedures, record keeping, what are differences between a company's good manufacturing procedures, the standard operating procedures and HACCP, what are the requirements. We basically touch on what the requirements are in this module.

The most important thing that we stress in this module is that industry has a variety of ways that they can look at their plants and develop and plan and that there will be a lot of variety from plant to plant and that inspection personnel should not count on the fact that one plan is going to look like another plan. They have to get used to the fact that different records will be used and different methods and different CCPs with each process. That is what is stressed in that module.

The next module, Module 4, is actually broken up into two parts. There is a Module 4-A, which talks about microbiological testing for E. coli. The purpose of this module is to inform inspection and compliance personnel on

the regulatory and operation requirements that the plants must implement on E. coli testing. Basically in this module we are talking about what the plant is responsible for. It gives the inspectors an idea of what the plants do as far as their E. coli testing.

The other part of this module, Module 4, is Module 4-B, which is the microbiological testing of salmonella. The purpose of this part of the module is to inform the inspection and compliance personnel on the regulatory and operational requirements of the salmonella testing.

Now, both of these two topics are discussed in a later module, and you will see as I go along. One of the things that we stressed in this module is the difference between microbiological control guidelines and performance standards so that inspection personnel would know the difference between those and get an idea as to when we enforce and when we do not enforce things.

The fifth module was one of the modules that was important as far as the systems approach and the regulatory model. The purpose of this module was to provide background to inspection and compliance personnel on the change to a systems approach to inspection.

Pat Stolfa already went into detail about the regulatory model. Basically this is where inspection personnel are first introduced to the regulatory oversight

model and the term FSI verification and the new way in which we are going to use that term for Basic, Other and Special. We also describe in this module different consequences of system failures, and we just give the participants a basic idea as we get into things how they are going to regulate under the HACCP system.

Module 6 is a very important module. It is called the Revised PBIS. The PBIS system has undergone a major facelift. This module is important for introducing all of the participants to the changes made to the PBIS system in order to support the new HACCP based inspection.

In this module we gave out the new directive, 5400.5, the inspection system activities, which hopefully all of you picked up. We spent a lot of time reviewing and reading over that module and that directive so that the participants could become familiar with all of the new terminology, how they can use what is now called their procedure schedules and filling out those procedure schedules.

We also started a workshop for non-compliance trend indicators so they could get used to those new terms, a non-compliance trend indicator, and to know what a non-compliance trend indicator is and how and when to use it.

The next module, Module 7, is called Basic

Compliance/Non-Compliance of Plans. The purpose of this module was to provide instructions to inspection personnel for determining whether a plant's plan is in compliance or non-compliance. In this module we discussed what the plant awareness meeting is and the importance of the plant awareness meeting and what the IIC is responsible for.

This was a very important module because it gave the people at the training an idea of what the regulatory requirements of the HACCP plans are. It introduced them to using in workshops the checklists that are in the 5000 directive and basically taught them how they can document findings and take enforcement actions. This module is actually the first module where they get to practice some of the new things that they were learning in some workshops.

In the next module, Module 8, which is called E. Coli, Basic and Other Compliance/Non-Compliance, the purpose of this was to provide instruction to inspection personnel for determining a plant's compliance or non-compliance with the pathogen reduction requirements.

As I said, this is the second time that E. coli was in a module, and this module actually goes over what the inspector's role is for E. coli testing. It shows them how to use the two checklists when they do basic or other compliance/non-compliance tasks and procedures and how to document their findings and take the enforcement action. It

also showed them how to use the non-compliance trend indicators for E. coli, which there are two of them, the basic and then the other.

The next module, which is Module 9, is the largest of the modules and takes up most of the training. It is called Other Compliance and Non-Compliance. The purpose of this module was to provide instructions to inspection personnel for determining a plant's compliance with HACCP, SSOPs, salmonella and other non-related HACCP and pathogen reduction requirements.

During this part of the module was when we handed out and reviewed FSIS Directive 5000.1 on the enforcement of the HACCP regs. This module was actually broken up into four parts. Module Part 9-A was called Salmonella Testing. In this module we discussed who does the testing, how do they do the testing, what are the species, what are the methods, the site, the storage and handling, everything applicable to doing the salmonella testing for inspection personnel.

In Module 9-B, we discussed Other Compliance/ Non-Compliance and basically went over a number of workshops that dealt with the Other Compliance/Non-Compliance and how to document and take the appropriate enforcement actions.

In Module 9-C, we reviewed the SSOP Other Compliance/Non-Compliance and defined and applied,

documented and took action in different workshops to get them used to the new SSOP Other Compliance/Non-Compliance aspect.

Finally, in Module 9-D we talked about the other consumer protection part of the program. Once again we defined the terms. We applied them in workshops. We taught them how to document and then how to take the appropriate action when necessary when not in compliance.

Module 10 was Technical Assistance and Advice. The purpose of this module was to provide instruction to inspection personnel on how to secure the technical advice and assistance from the new Technical Service Center which will become very important as we move into more technical aspects of the program.

Finally, the last module, although it was not presented last, is Module 11 called Business Relationships. The purpose of this module was to provide information and techniques to participants for use in building effective relationships, managing conflict more effectively and communicating more effectively.

As I said, although this was Module 11, we actually decided when we were down in Texas to do this on the second day because building effective relationships is a very important part of our jobs and is something that needs to be stressed.

In our regulatory roles we come across a lot of conflict in our jobs sometimes, and it is important for all of us to know how to deal with that and to work and focus on issues and not on personal value systems and to be successful in order to work with other people and build trust through communication and also to learn how to demonstrate active listening skills because not only do we need to be able to stress the different things and talk to people, but we also need to be able to listen to them.

That basically outlines the 11 modules that we are presenting as facilitators in the field. So far in the sessions where I have facilitated, the participants have been very positive, and it seems that the material is going over very well. We have had some questions, but all of the questions seem to be answered, and everyone seems to be comfortable with the material.

At this point I am going to turn the microphone over to Dr. Masters, who will discuss the two additional components of the HACCP technical training and implementation, the supervisory and enforcement conferences.

DR. MASTERS: Good morning. As Dr. Arnold indicated, I am going to talk about the two other portions of our Agency training package for HACCP implementation. The two components that I will talk about I know both Dr. Mina and Mr. Smith feel very strongly are essential

components to a successful implementation of our HACCP.

The first piece is a supervisory conference on HACCP implementation. This conference is scheduled to take place the first week in January, and all of our district managers, as well as each of our circuit supervisors, will be in attendance at that training session.

There are designated pieces that the circuit supervisors will take home from this supervisory conference to share with all of our field supervisors out in the field, so everyone will benefit from this session.

The purpose of getting all of our front line supervisors together is to continue reinforcing the fact that they are out there to lead the change. It becomes even more important for them to lead that change as we move into the HACCP work environment.

There are four primary areas in which the culture change will be discussed during this session, the first of which is to generate motivation and buy in for the Agency direction and change in the role of our supervisors. We will also be discussing an understanding of employee empowerment and what that means to our supervisors.

We will be talking about identification of the paradigm shifts, spending a lot of time talking about moving from command and control to performance standards and how supervisors should act in that sort of environment and to

make it known to all of our supervisors that open and collaborative behavior is expected from them.

Another component of the supervisory training conference will be a systems approach. We will be spending a considerable amount of time in providing supervisors with an understanding of the differences between regulating in a command and control environment and regulating in a systems or a performance standard environment.

We will also be spending time describing the components of the inspection process, spending time in the new implementing directives and the inspection system procedures guide.

A very important part of this training is to make sure everyone understands their roles and responsibilities as we implement HACCP. We will be defining and describing those roles and responsibilities for all levels of our field supervisors from IICs up through the district manager and what those roles and responsibilities are in the HACCP work environment.

We will have a section covering the application or the performance management, and that is to help insure that our supervisors understand how to apply the principals covered in previous units in managing the performance of employees and supervisors at the circuit and in plant levels. The way we have captured that is the concept that

we are working on the system rather than in the system.

The final part of our overall big picture for our technical training for HACCP is an enforcement conference on HACCP implementation that is tentatively scheduled for February, and that is a conference that would include our assistant district managers for enforcement, as well as our supervisory compliance officers. The intent of bringing that group of personnel together is to insure that they understand their role and the partnership arrangement that is necessary to carry out the procedures in our implementing Directive 5000.1.

I think you can see that we have a very comprehensive training package. I am a person that is designated to work with facilitators like Dr. Arnold, and I am very pleased to say I speak to them on a daily basis in large numbers. They are very positive. I would say things are going very, very well. I think we are getting all questions answered, as Dr. Arnold indicated.

We are working closely with Ms. Stolfa and her staff if policy clarification is necessary, and I would say we are well on our way to a very successful facilitation process.

Thank you.

MR. SMITH: Thank you, Ilene and Barb.

What I would like to do now is work through our

regulatory process, our Agency verification. We will discuss the regulatory process for HACCP based inspection.

I will tell you just like we had what was referred to as the little green book SSOPs, hopefully this week we will finalize a similar publication for HACCP on salmonella and E. coli. Basically what will be in that book will be the regulatory model we are going to go through, the regulations and the two directives.

We do hope to have that out shortly, and hopefully by next week it will be on the Internet first and follow through publication. The Internet address is on the table out there. I would encourage you that after Monday or Tuesday of next week to look for that.

I want to talk about the regulatory process. Just like we had with the SSOP, we have a regulatory model. The first block I want to focus on is on Block 2 where it says FSIS Conducted Awareness Process. We see this as an extremely important process for implementation of HACCP.

On January 26, inspectors and plant managers are expected to sit down and go over the HACCP plan. We have given anywhere from one to four days for this process to take place, so my guess is that what will happen is that inspection personnel will be responsible for performing verification activities that we are going to be talking about, will perform the SSOP procedures and then will sit

down with plant management and go through that plan to become familiar with how the plan was developed, what records will look like, where records will be kept, who is responsible for what, what designates a monitoring person in the plant, what designates a verification person in the plant, how the pre-shipment review process will take place because that, as you will see later, is a critically important component of regulatory determination.

Basically the goal is to have a full understanding of that HACCP plan in that plant. We realize there are 6,500 plants out there. We realize there are 6,500 different ways of applying those seven principles in HACCP and that you have designed them to work in your plant. Before any regulatory determination can be made, this plant awareness process must take place.

Again, we are strongly encouraging our people, again anybody assigned to the plant that is performing inspection activity, to participate in this plant awareness process. We hope that your management team will also avail themselves of this opportunity and have full participation because we see it as a critically important component. This process will be done before any regulatory determination can be accomplished by our people.

Once we have completed the awareness process, we move into our basic compliance determination. This is the

checklist that Pat Stolfa talked about earlier to see if it meets the regulatory requirements, the plan meets the regulatory requirements. If the answer is yes, we will move over to other procedures.

If the answer is no and basic requirements are not met, then FSIS inspection personnel will initiate a withholding action withholding the marks of inspection in the plant. This is similar to the process that we did with start up of SSOPs. When we have plant compliance, FSIS will remove the withholding action. That pretty much defines our basic compliance determination.

What I would like to do now, because we are into the process here where FSIS performs other procedures, is sometimes what is very helpful for the rest of my presentation is I like to do a visual enactment of exactly what we will be doing. I am going to ask some of my Food Safety Inspection Service colleagues to help me. We are going to do it right back here.

I am going to ask Barbara Masters and Ilene Arnold and Mary Cutshall if they would stand here just together. What they really represent are we are going to call them the CCPs. Barb and Ilene and Mary are either there to eliminate a hazard, control a hazard or reduce a hazard. They have been established as critical control points, and each one has a critical limit.

I am going to ask Jeanne Axtel to come up. Jeanne Axtel is going to represent plant monitoring. As we go into the program, it defines monitoring activity, frequency and how it is going to be done. Jeanne at the defined frequency in the HACCP plan will be monitoring the Barb CCP and the Ilene CCP and the Mary CCP. She will be documenting her findings at the specified frequency.

I am going to ask Perfecto Santiago to come up and help us out. Perfecto is going to represent plant verification. Perfecto's job will be to insure that Jeanne is carrying out the monitoring activity at the defined frequency and that Jeanne is recording the records of her monitoring activity.

In addition, Perfecto may have some other duties. Especially and most critical would be corrective action. Let's say we had a critical limit deviation at the Ilene CCP. The regulation defines four actions that get carried out, Plant Corrective Action, 417.3. The verifier would insure that those four actions for plant corrective action were carried out.

If we encountered an unforeseen hazard, 417.3(b) defines four actions for unforeseen hazards, including reassessment and possible modification of the program. Again, the verifier, in addition to seeing to the monitoring activity, is responsible for that.

We would also say that the Barbara CCP let's say represents a complex piece of equipment. Let's talk about a heat exchanger. It needs to be calibrated at a certain frequency to insure the adequacy of measuring that critical limit. Another role for the verifier is to see that that calibration activity is done and documented at the frequency defined in the HACCP plan.

There may be other things. Some plants may do some microbiological profiling at a particular HACCP. All of that goes under the plant verification activity.

I will ask Charlie Gioglio to come up here. What Charlie represents is the pre-shipment review. That is extremely critical. Before a specified production or product leaves the plant, Charlie's role will be to check the documentation to insure that the critical limits of the Barb CCP, the Ilene CCP, the Mary CCP, were met, that Jeanne's monitoring activity took place and was documented and that any work that Perfecto had associated with determining those critical limits were met would all be determined by Charlie.

Now, I will play the inspector role. What is my role? My role is to verify that all the activities that we just talked about took place. We will do that through performance of the two PBIS procedures that Pat talked about earlier. We will go through those now, and I would like to

thank you for helping me out.

Again, what inspection personnel will be doing then is verifying that the plant has met monitoring, verification and record keeping requirements and that when a deviation is found they verify corrective action and that reassessment requirements have been met for every deviation; again deviation being defined as a deviation from a critical limit.

As Pat said earlier, we have two procedures for doing that, the 01 procedure of reviewing a random sample of the regulatory requirements and operation, and inspectors can either do that through observation or hands on inspection tasks that Pat referred to, or use a record keeping or both, any combination. An example would be that they could review CCP records for different lots of product. They could review calibration records for considering the procedure complete.

What is important and we want to point out at this point is that a system determination cannot be made using an 01 procedure because it looks at specified parts of the program, but not the entire program. If there is a non-compliance determined, and we will go through this in the regulatory model shortly, but just to point this out now if a non-compliance is determined in performing the 01 procedure, inspection personnel have been trained to perform

an 02 procedure.

An 02 procedure can either be scheduled where it will look at the entire process under the HACCP lot or shipment or specified production under the HACCP process from start to finish as Pat said earlier, or as a result of finding non-compliance in an 01 procedure because if we find a monitoring problem, a critical limit deviation, we need to know that 417.3 was carried out and any verification activity associated with that. The inspector will automatically then perform an 02.

The 02 procedure looks at an entire lot or shipment. It is not random. As Pat said earlier, it verifies all requirements and determines that the establishment is following the HACCP plan and determines that the establishment personnel are performing the task in the plan. It also verifies that corrective actions are taken, that the pre-shipment reviews are completed and determines if the HACCP plan prevented distribution of adulterated product.

We have been instructing our folks that there are basically three barriers that are in place -- monitoring, verification and pre-shipment review. If we have a critical limit that was not met resulting in a deviation and it gets through monitoring, verification and pre-shipment review, then we would determine that the HACCP plan did not prevent

the distribution of adulterated product.

As part of an 01 or 02 procedure, we have taught that there are two components to that. There is either a review and observation, and that is where inspectors can observe activities occurring in the production areas, they can compare the results of those observations with production documents, they can perform a number of on site tests, and these are just a few, of taking temperatures either after cooking or in the coolers, comparing their results again to the HACCP plan record, or directly observing establishment employees performing the activities defined in the HACCP plan.

We also say there is a record keeping component. Those record keeping requirements are defined in 417.5. There is a record keeping component for monitoring, there is a record keeping component for verification, a record keeping component for corrective action, a record keeping component which defines what should be seen on records, and again a part of that is the pre-shipment review.

As Pat said earlier, we have two procedures in HACCP, 01 and 02. They are built on the nine process categories that were defined in the reg. They are listed sequentially, so B, C, D. The 01 and the 02 are the same process no matter which particular product category it falls into.

Just so you remember those nine processes for HACCP plans, we have listed them here. They are slaughter, raw product-ground, raw product-not ground, thermally processed, commercially sterile, not heat treated-shelf stable, heat treated-shelf stable, fully cooked-not shelf stable, heat treated but not fully cooked-not shelf stable, and product with secondary inhibitors-not shelf stable. Remember again that the 01 and 02 are identical for all nine processes.

If we go back to our regulatory model then, we have performed an 01 or 02. The first question the inspector has to ask then is non-compliance found. If the answer is no, then we stop and go on to other activity. If the answer is yes, we have completely eliminated deficiency classification. What we are interested in is whether we have a system failure or not.

If we determine that we do not have a system failure, then we will complete a non-compliance report. The non-compliance report replaces the process deficiency record, but again as in the process deficiency record we would expect plant management to respond with immediate and further action to prevent reoccurrence of the non-conformance, and we will perform then our procedures.

Again, if it was an 01 procedure that we found a non-compliance on we would immediately go to the 02

procedure. If we determined we had a system failure, we could complete the non-compliance report and take a withholding action on the plan or processes or products affected under that plan, and in that scenario the IIC would contact the district office.

What are those actions that we would be determining when a system may be inadequate? The first one, the plan of operation does not meet requirements. That really is more the basic where we said that the first determination is that inspection personnel determine that through their checklist that all parts of the required plan are there.

We talked about earlier if adulterated product is produced or shipped. That is where we talked about again if we had a critical limit deviation, the deviation was not corrected and picked up on monitoring, was not corrected through verification or not picked up through pre-shipment review. By definition, we have adulterated product that is produced or shipped.

We also then had other areas where we would determine that we have an inadequate system. Basically establishment personnel are not performing specified tasks. There would be the monitoring frequency if we are not monitoring according to frequency or documenting our monitoring activity.

The establishment fails to take corrective action, and again corrective action is defined in 417.3 both for when you plan if there is a deviation from a critical limit and also B talks about an unforeseen hazard. There are four steps to each of those. Inspection personnel will be verifying that all four steps in either 417.3(a) or 417.3(b) are carried out or that HACCP records are not being maintained.

Would we do this on one finding? Probably not, but we will make the determination if we document that monitoring activity as defined in the plan is not being carried out or verification activity in the plan is not being carried out or record keeping.

We would provide notice on the non-compliance record, and if we have a repetitive pattern of that occurring again we will provide notice and we will be focusing on that this is a regulatory requirement, that the HACCP plan says they will be doing these things and that from previous notices on the non-compliance record the plant was going to implement immediate and further action to prevent recurrence, and they are either failing to execute that corrective action because we are still having the same problem.

When we have that repeated problem again of a regulatory requirement not being met, not executing the plan

as you yourselves have defined it and not executing corrective action to eliminate the problem, when we have that history then we would determine that we have an inadequate system. That is what is represented by establishment personnel not performing tasks, specific tasks, establishment personnel failing to take corrective action, HACCP records not being maintained.

In the situation where we have taken a withholding action, then the district office, just like we have done with SSOPs, will assist a compliance officer. They will sit down and document a case file, and then the district office will be the first level to determine what further actions will be taken. That district manager will be advising the plant of what those actions will be in writing. Those actions could be anywhere from suspension through withdrawal.

We do have other regulatory requirements. We still have our wholesomeness checks. We still have our economic adulteration responsibilities. We still have our labeling responsibilities. We have a different regulatory model for these because again remember that we have eliminated the deficiency classification guide.

What inspection personnel will be doing is performing their inspection procedure. If there is non-compliance found, they will take whatever official

control actions necessary. They will complete their non-compliance report, and there will be an expectation that plant management will respond with corrective and preventive action.

The action will be taken on the specific product. It is not a systems determination when you're dealing with a wholesomeness, economic adulteration or labeling, so our actions there are similar to what our actions are today in those arenas.

I apologize for this particular slide. I do not know what happened there, but this is a comparison of PBIS previous to HACCP and under HACCP. The old directives were 5400.1 and 5400.2, 8800, 8800.3 and 8800.10. They are now replaced with the directives we have been talking about. Directive 5000.1 is the HACCP salmonella SSOP and E. coli implementing directive, 5400.5 is how PBIS will work to support HACCP, and 8800.2 is our general overall introductory PBIS directive.

What then you will see is that under the current system the inspection system guide is set up with processes, CCPs and tasks, inspection tasks. Presently there are 540 inspection tasks. In the new setup under the inspection system procedures guide we will have activities, elements and inspection procedures. We have replaced those 540 inspection tasks with 48 inspection procedures to cover the

entire range of food safety, wholesomeness, economic adulteration and labeling.

As we said earlier, under the current system we focus pretty much on defect identification. We have used the deficiency classification guide and documented our findings on the PDR. We have usually listed those findings as Minor, Major and Critical.

Under HACCP, and I again refer you back to our regulatory model, we will make a determination whether we have a system inadequacy or not, and we will document our findings on a non-compliance record. We will use the non-compliance determination guide to identify the findings, whatever findings, but they will be our findings.

If we do not determine we have a system inadequacy, then they will document whether we are dealing with a monitoring problem, a verification problem, a record keeping problem. In the wholesomeness, economic adulteration or labeling arena we have specific non-compliance trend indicators. They are in 5400. The non-compliance determination guide is there. What the inspector would do is determine which of those trend indicators are most applicable to the deficiency that they found.

Under our current system, if a plant identifies corrective or preventive actions and when we had an

extended history of repeated non-compliance we used the progressive enforcement action with the exception of the SSOPs. The SSOPs were the basis for the enforcement model. It was our first enforcement protocol, and we have now moved our entire under HACCP system to that enforcement protocol. The plant would identify immediate and further planned actions to prevent a system failure or non-conformance. We have defined our enforcement protocols previously in the regulatory model.

I believe that is what I have as far as the process. I believe we are at a break now, and then we can come back now and do our Q&As.

MR. BILLY: Let's break for about 20 minutes, and then we will get into the Q&As.

(Whereupon, a short recess was taken.)

MR. BILLY: I would like to get started again. If everyone would take their seats? We are going to get started again.

We realize that we have covered a lot of material already. Several people came up and asked if it would be possible to provide copies of the slides, so we are going to do that. That is being worked on now, and we will have that available for you.

We also want to encourage you to take time as you can to look at the materials that have already been provided

this morning. When we get to the afternoon session, you will notice there is an awful lot of time towards the end. It is fair game to go back and bring up issues that were provided in the materials this morning.

As you get a chance to look at the directives and the other information, feel free if you think of something you did not think of this morning. It is not a lost chance. You can come back at it. It is about trying to communicate and share information with you. We want to facilitate that as much as possible.

Mark Mina wanted to add a couple of points regarding the training to get started.

DR. MINA: We have embarked on an extensive training, as you have probably seen a little bit earlier this morning, for our inspectors. In addition to that, we wanted to provide the opportunity for industry trainers if there is interest on industry's part to assign people to conduct their own training. We shared the same material we give to our inspectors with industry trainers.

We had one session the first week in December at College Station. It was fairly well attended. I understand we had about 80 people that participated in that training. We are scheduling another session January 13, 14 and 15. If there is interest, you need to contact Terry Harris from the HACCP Alliance and indicate specifically that you are

interested in the FSIS training program.

We go through the same detail we go through with our inspectors in the training so there will be a common understanding of what we train our inspectors on.

MR. BILLY: Yes. It is essentially taking the eight days of training and compressing it into three, but going through the same materials. Since these are HACCP trainers they are pretty familiar with a lot of the material, but it gives us a clear sense I think of how we are providing the information and how we are answering questions and that kind of thing.

Let's open it up now. What I would first like to cover would be the HACCP training area, given the material that was presented by Ilene and Barb, and whether you have any questions about our training, our strategy, approach, how it is working, material that was actually presented to you here this morning.

Are there any questions about that? Rosemary?

MS. MUCKLOW: Tom, I think it was Mark who said that you have 1,700 people to train. You have about 600 already done. You are moving into the balance of them.

You have not mentioned at this point the GS-7 people that are not being trained. As you know, that has been a major matter of concern to the industry. Can you please tell us what kind of training or information or

guidance or instruction?

All of those people carry the mark of inspection, wear the mark of inspection, wear the badge of inspection and have authority under the law. Our industries have been very concerned that they may not be as well informed and yet have every right as a Government official to take regulatory action. We would appreciate your clarifying that for us.

MR. SMITH: We have not completed all our employee interaction and discussions, but our proposal and what we are training and going forward with is that only GS-8 and above employees will be trained in HACCP because they have off line duties.

Our GS-7s perform antemortem and postmortem inspection, and that is not affected by this HACCP implementation. Therefore, there is no HACCP training that needs to be delivered at this point.

MS. MUCKLOW: So they are getting nothing at all?

DR. MINA: They are getting some things, Rosemary. They are not getting the full blown eight days of training. However, we doing a couple things with the GS-7s.

One of them that I have emphasized to the district managers as extremely important is for us to communicate, particularly during this period of change, particularly communicating with the in plant inspectors and inspector in charge, and that responsibility lies on the circuit

supervisor as was mentioned earlier.

We will have a supervisory conference in January, and this is one of the points that we want to emphasize to them. To that end, we have told the district managers they can hold work unit meetings with the in plant inspectors and inspectors in charge throughout the country. This is an expensive proposition, but we have funds allocated for that purpose.

We want to make sure that everyone in the plant understands the direction and the philosophy and the cultural change that we have been talking about in Washington. That is not necessarily training per se, but that is going to put them on equal footing in terms of understanding the direction of where we are going.

In addition to that, we will eventually train the GS-7s, but that is tied to the HACCP pilot process.

MS. MUCKLOW: Are you providing any written materials to them? If so, can we be provided with those?

DR. MINA: Well, they would be provided with probably at least the questions and answers that we have been getting from the field. That is distributed to anyone and everyone.

MS. MUCKLOW: The what?

DR. MINA: Questions and answers that we get through the facilitator when they conduct training. All

these questions are raised, and we respond to those.

MR. BILLY: Okay.

MS. NESTOR: My name is Felicia Nestor, Government Accountability Project.

Dr. Mina, you might have just answered part of my first question, which is when Dr. Arnold was reporting that the training had gone so smoothly, I had gotten a different impression from the inspectors that I had spoken to at the train the trainers session and also the subsequent training of the inspectors sessions.

I was just wondering whether someone would comment on that? There seems to be a discrepancy between everything is fine and what I am hearing from inspectors and what is on the inspector home page.

Now, you say that there is a series of questions that have been collected, and they will be answered so that --

DR. MINA: Yes, that's correct.

MS. NESTOR: -- the very important questions that the inspectors have about this will be written down and answered? Okay.

My second question is this. In your conference for the supervisory personnel, you mentioned a buy in. I am assuming what that means is support from the supervisors for this program is required. I am wondering. That does not

give the impression of being open to changes that are being demanded or seen as necessary by the front line personnel.

I know that there are a lot of concerns with the way SSOPs were implemented. If you make one of the performance standards for a vet that they have to buy into this program and support it 100 percent, that does not leave room for improvement, as far as I can see, from people that know what is going on in the field.

DR. MINA: Let me address your question, Felicia, on the training. Dr. Arnold was quite correct in describing the positive aspect of the training. I would be less than truthful to say here that 100 percent of the trainees understood perfectly everything we taught them.

We have some questions because of the complexity of the training, and probably the eight days is not going to satisfy every inspector in terms of receiving this complex training. We intend to address those issues on a case by case basis and make sure that everyone has that common understanding of what is expected in terms of implementing HACCP and how they perform their job on January 26.

That is not going to be the end of the line. We are going to go back and take a second look at how the training was implemented and review that and make adjustments and tweak it. That is what we talked about earlier about beginning the implementation process on

January 26.

Your second question was about buy in and a question about whether we have 100 percent buy in. We have a large work force, as you all know. Selling and marketing new ideas and new concepts requires this extensive communication process. I am confident, and I am going to tell you right here that I think most of our work force are committed to the HACCP implementation and the concepts of inspections in the future.

Change is not easy. People perceive change in different ways, and they accept it and adapt to it in different ways. This is a difficult process for any organization that goes through training. It is not unique to FSIS or this particular industry. That is a normal process, but we will overcome that, we are very confident, because of the things that we did to prepare for that change.

MR. BILLY: I think it might be useful to ask Ilene and Barb to make any comments as well.

DR. ARNOLD: Yes. I would like to at least make a comment about the train the trainer program because I was also involved in that and was down in Texas to help train the new facilitators.

In my opinion, that program was excellently put together. The week of training that the new facilitators

had was excellent. The material that was given was excellent. The people that I spoke to while I was down there and actually helped train had a very positive attitude.

I am not really sure who you spoke to. I know that there were one or two people that really didn't want the job of being a facilitator, and maybe that's who was being negative about it. Most of the people are very enthusiastic about being facilitators, about the change and being involved in the change process.

As we learned last year in our first module about moving through change, there are five stages that we go through when we go through these changes. Even some of the facilitators are going through the change.

I know that when we first were presented with the material a lot of people have the reaction that oh, this isn't going to work, but then they see how it works and go through the bargaining and the different stages. I know that by the end of the three weeks when we left to go out to facilitate the new material that we had been given, everybody had accepted their job and their responsibility and were enthusiastic.

I think being a facilitator myself that I am enthusiastic, and the people that I help facilitate and train with this material feel the enthusiasm that I have for

the material and, therefore, I impact a positive attitude. It helps them through the change process. I think that that is a very important step when you are a facilitator.

I'm sure that of the 120 some odd facilitators there are a few facilitators that are not as positive as I am. If you're not positive, that will affect the people that are participating in the facilitation. With any program, nothing is perfect. I am sure there are those people out here, and, of course, those happen to be the people that are on the Web and are the people that want to have the negativity associated with the program.

In my opinion, the people, as I said, that I am working with are very positive. The material is positive. I hope that the next session that I facilitate will continue to be as positive as the one that I have facilitated. That is all I can comment on.

I know that the people that I communicate with on HP Desk that are other facilitators have had similar experiences. That is the experience that I like to talk about, and I like to be positive so that we do have a positive outcome.

DR. MASTERS: The only thing that I would add to that is that in addition to the three week process that we had for our facilitators, when they were sent back to their duty stations we provided an additional 36 hours for them to

go through the materials to make sure they were comfortable with the material and understood the material and were available for any questions that came up as they went through the materials.

I think a lot of people when they went back and had that opportunity felt much more comfortable with the material, and that helped in their ability to go out and facilitate.

Additionally, this year we have put in place an audit program where we are out auditing facilitation sessions. We have been out for the last two weeks doing that, and so far people are following the facilitation program properly. We are finding with the people we are talking to and the places we are visiting that things are going very well.

MS. SIEMENS: Angie Siemens with Oscar Mayer Foods.

You have already mentioned that we have had 600 inspectors already trained. Barbara, you also mentioned that through the training you have had various policy issues come up and clarifications that have been made.

I understand that we will have supervisory training not until the first full week of January. How are you going to communicate back to those inspectors the policy decisions and clarifications for those folks that have

already gone through the training?

MR. SMITH: We have a couple of things in place. One is every HACCP plant or plant that comes under HACCP implementation, every large plant now has a computer and is on our e-mail. As we have our Q&As and work with if there is a policy change after they've been trained, that will be instantaneously communicated to all 304 plants simultaneously at the same time.

We will also reinforce if there is any significant variation or change. That will be communicated at the supervisory conference and then will be one of the things that people would be looking for when we implement our supervisors to see that that has been communicated.

Each facilitator in the country now has a laptop computer. Like I said, each plant where we are implementing HACCP has a computer. We can communicate instantaneously with all these people at the same time.

MR. BILLY: Kim?

MS. MUCKLOW: Rosemary Mucklow, National Meat. Just to follow up, Bill, there was some discussion about maybe doing some correlation between industry and inspection to try to make sure everybody is seeing the same thing through the same eyeglasses. Is that going to happen, or is that just a pipe dream?

MR. SMITH: I think that is one of the major goals

we are trying to get out of the planning awareness meeting. The plant and the inspection team at that plant sit down and go through that plan. I think that will accomplish that goal.

MS. MUCKLOW: But any national correlation, any trying to bring this together, you know, of the seesaw? That guy, he did it differently. We have had that for years. You know that.

MR. SMITH: Again, I think as Mark was saying we always get constant feedback. Through these public meetings is a good way of doing that. We are always open to the associations bringing this in, and then we can through working at meetings or through our electronic communication capability that we now have, we can correlate that.

We will be doing an evaluation of HACCP just like we did with the SSOPs, and then if there are strengths or weaknesses we need to work on we will address them through that. There are a number of ways of doing that.

DR. MINA: If there is a need to correlate in a specific location, a specific situation, we are willing to do that, Rosemary.

In addition to that, what we are planning to do also is to follow up on the implementation like we did with the SSOPs. It is premature to schedule that right now, but a few months after we implement I think we need to go back

and see what we did and make some adjustments if they are needed.

MR. BILLY: I assume this will also obviously impact the training that will commence right after the first of the year for the next set of plans, so this will be a continuous refinement process as we work through implementation of HACCP, through all the plans. This is not one shot. This is a whole process that is underway.

I have Angie, and then Kim, Howard and Dane. Angie?

MS. SIEMENS: Angie Siemens, Oscar Mayer Foods. Just to follow up, I know you are doing the communications to the inspectors via the laptops and the Q&As. We also had the industry training that you put on a couple weeks ago.

How can the industry also be made aware as those policy changes are made so that we are on the same wavelength as where you are?

MR. SMITH: First, we are not seeing major policy changes. I don't want to have a major misconception. It is more interpretation or a question on how we are doing something.

I think Pat has already explained any policy determinations would be through Federal Register notice, so the industry would certainly be notified of those. I do not see inspection methodology having been explained in the

implementing directives. If there is in training that we are doing something different, and I'm not sure what that would be, but if anything would come up we have the International Alliance for communicating in our training.

I'm sure we will publish in the white papers or Federal Register notice anything that we would be changing so the industry knows what we're doing.

MR. BILLY: Kim?

MS. RICE: Kim Rice, American Meat Institute.

Can we go back, though, just for a second on those interpretations? I think those would still be useful for the industry to have as well.

MR. SMITH: I think we provided Q&As on SSOPs, and I don't see why we couldn't do that with HACCP also.

MS. RICE: Okay. Could you spend a few minutes on the new non-compliance record in just going over it? I have some questions, and I do not want to jump into the questions before everybody in the room understands the new system.

MR. BILLY: Can we hold that until after we finish the training --

MS. RICE: Okay.

MR. BILLY: -- unless it is how we are training on that? Is that your question?

MS. RICE: No.

MR. BILLY: No? Okay. We will come back to it.

MR. MIRTSCHING: Warren Mirtsching with Monfort.

Question for Dr. Masters. You have supervisory conferences and enforcement conferences that are going to take place in January and February. You made reference that the roles of each of those individuals was going to be explained to them. Is that already in documented form, and is it available to industry?

MR. SMITH: Could you repeat the question, please?

MR. MIRTSCHING: The question is you have supervisory and enforcement conferences scheduled for January and February. Those are guidelines or roles that are going to be communicated to those individuals. I would like to know if that is documented and available to the industry.

MR. SMITH: Again, I think we have always made our training available. We have not completed that yet, but when we do have our materials completed then we will make those available like we do all of our training material.

MR. MIRTSCHING: Thank you.

MR. ISLEY: Howard Isley, Widmark Foods.

Bill, I have a question dealing with communication, electronic communication. Throughout the United States we have several TA plants which are large, in excess of 500 employees. Are they considered also in terms of this electronic transfer in terms of laptop computers?

MR. SMITH: Yes. TA plants are federal plants, and, yes, they will have the computers in place and will be on the same communication network as everybody else.

MR. BILLY: And I assume the inspectors are being trained as part of this for the large plants?

MR. SMITH: Yes.

MR. BILLY: Dane?

MR. BERNARD: Dane Bernard, National Food Processors Association. First of all, I compliment you on your recognition of the need for ongoing training. I think we are all going to learn more about HACCP in the next year than maybe we care to, but certainly more than we have in the last ten years.

It might be worthy of consideration that the need for additional information might go beyond what can be done by simple e-mail. You may have to think about some more intense types of training somewhere down the line.

Questions. Mr. Billy, you may want to hold these until later, but it came up during Dr. Arnold's presentation. The mention of non-compliance trend indicators came up in relation to PBIS in terms of E. coli testing.

There was another reference that I would like a little clarification on. Again, it is up to you as to whether you want to do it now or hold it until later, and

that was Training Module 9-D on consumer protection portion. I would just like a little clarification on those terms, if I could get them.

DR. ARNOLD: That actually relates back to the non-compliance report. There is Block 9 on that report. I believe in the 5400.5 there is actually an example of that. I am not sure. I don't remember exactly what page it is, and I don't have that in front of me, but it is one of the attachments.

MR. SMITH: Attachment 3.

DR. ARNOLD: Attachment 3 is what I am being told. If you look at that non-compliance report, you will see that on Block 9 that there are a number of different blocks relating to SSOP and HACCP. Does everybody see that?

MS. MUCKLOW: What page is it?

DR. MASTERS: Page 29 in 5400.

DR. ARNOLD: Do you see that? The title of Block 9 is Non-Compliance Classification Indicators. When we talk about the non-compliance trend indicators, those are the indicators that the inspectors are learning about and learning how to use in the training session.

MS. MUCKLOW: I do not think we are all on the right page. Some of us are slow.

DR. ARNOLD: Page 29, 5400.5, the inspection systems directive.

MS. MUCKLOW: We were in the wrong book.

MR. SMITH: Actually, the non-compliance determination guide is Attachment 5 to this directive and is starting on Page 35. We will be glad to go in depth on that.

MS. MUCKLOW: We are on the right page. Now you can talk.

MR. SMITH: We will go in depth I think once we move from the training on that.

MR. BILLY: Yes.

MS. MUCKLOW: You will tell us later now that we found the right page?

DR. ARNOLD: I just wanted to tell you that when I reference that in the training material, that is the portion of the non-compliance report that the inspectors are actually learning about what they are and how to use those. The definitions are also in this material.

MR. BILLY: Since we are here, why do we not work through it? Then we can get it off the table.

MR. SMITH: Okay. If you go to Page 29, the non-compliance record, it is set up and looks a lot like a process deficiency record. They identify the name and title of the plant, and we document relevant regulations.

You can see there is a piece there whether your non-compliance is in HACCP, SSOP or Other. This is where we

depart from the process deficiency record. We used to have the deficiency termination guide, and you would answer those three questions and determine whether you had Major, Minor or Critical. That is all gone. That has been replaced by non-compliance classification indicators.

For SSOPs you can either have monitoring, corrective action, record keeping or implementation non-compliance. That is defined in that attachment. I do not know if we want to go into each of those in detail, but I think it is pretty well defined in Attachment 5.

In HACCP, you can have a non-compliance in monitoring, corrective action, record keeping or plant verification. Those are the things we talked about this morning. If we had a verification non-compliance that was not carried out, that block for Plant Verification would be marked.

We have Product, and that is where under Product our product wholesomeness and economic adulteration issues are. If you have a non-compliance with a product outside of a food safety issue, it is either an economic adulteration, a mis-branding or protocol. We have certain things, certain processes like injecting emulsified trimmings, that are done under special process, so there is a non-conformance one of those. That block would be marked there.

For Facility, again we either have lighting,

structural or outside premise, or product based non-conformance. The product based would be today we have defined an SSOP and we have always defined an SSOP failure as a direct product contamination. If we don't have direct product contamination then we don't have an SSOP failure, but we still have a non-compliance with the regulatory requirement. That's where that would go is under Product Based.

With E. coli, it is laid out in the directive that the plant should be taking samples, recording results. If that is not being done, that is where that would be marked as a non-compliance.

There is a whole in-depth description, but basically you identify what your non-compliance relates to. In SSOPs and HACCP it is either monitoring, corrective action, record keeping or implementation. You classify and put it on one of those. With the others, again if we're dealing with products and it's not a food safety issue then you either determine whether you're dealing with economic adulteration or mislabeling. With the facility, again lighting, structural or outside premise or product based.

That replaces classification. There is no more, and I will say it again, Critical, Major, Minor. That is gone with the implementation of HACCP.

MR. BERNARD: Thank you, Bill. A follow up, if I

may. Dane Bernard, National Food Processors Association.

There are a number of questions that come up when you begin to look at this. One is the implications of a non-compliance in the A and B categories, which are SSOPs and HACCP. I am presuming that we are looking at those in relationship to, you know, likelihood of health risk versus maybe a letter concern on the part of the Agency. I would like your comment on that.

The words trend indicator that were used in the description in what you are training, non-compliance trend indicator, I am wondering if there is in fact what statistical process control people would look at in terms of some trend analysis on data. That is kind of what triggered my initial questions. Thanks.

MR. SMITH: And that is the purpose. The Agency will, because we have on the PBIS schedule. These trend indicators will be marked, and we will create a data base, and we will be doing trend analysis on these.

MR. BERNARD: Any comment on the first part of the question in terms of the categorization, SSOP/HACCP non-compliance versus consumer expectation non-compliances, other regulatory matters?

MR. SMITH: I think we have done that with our regulatory models, and that is why I had two regulatory models up there.

SSOP and HACCP was where we had a systems determination. If the system was determined to be inadequate from the Food Safety perspective, then we were using our withholding the marks of inspection and that enforcement protocol.

That's where I said for things like product facility that we would be taking our normal actions so they would be product based. If we had let's say a net weight deficiency, the action would be taken on that lot specific to that net weight problem, not all the products in the plant but from the Food Safety perspective.

Yes, A and B are significantly different and have different enforcement protocols than C, D and E.

MR. BILLY: And we will get more into that this afternoon, into a little more detail on A and B.

Katie, the same point?

MS. HANIGAN: Yes. Bill, could you clarify? I guess I did not hear. The box next to E. coli that says Other, what did you say falls under Other, please?

MR. SMITH: That would be the plants are on an ongoing basis sampling at the frequency that has been identified, that they are recording those results and that they are reacting to those results as listed in the regulations.

MS. HANIGAN: Thanks.

VOICE 1: Could you repeat that, Bill? We can't hear very well back here.

MR. SMITH: That would be where plants are taking their samples at their specified frequency, maintaining the techniques that maintain the integrity of the sample, that they are recording their results and that they are reacting to those results either through if they are expunging statistical process control or excision, M&Ms, or in poultry in the case of boilers they only have an M&M option on that. There is a checklist for that as Attachment 5 of FSIS Director 5000.1.

MR. BILLY: Are either of you going to ask questions on the same topic or a different topic? The same topic?

MS. NESTOR: On training.

MR. BILLY: On training? Okay. Any other questions about this particular area? We will continue on training, but I mean on this particular issue or question. No?

Felicia, you are next then.

MS. NESTOR: I heard awhile ago that not all the inspectors have been trained in SSOPs. Is that correct, as far as you know? If they have not, what percentage still have to be trained in SSOPs?

My second question is I know you did your SSOP

evaluation. Part of that was finding out from inspectors how they felt the training went, what they thought might need to be changed and then also a review of how they were in performing the new tasks such as writing the descriptions on the PDRs.

I am wondering. Did you find that their assessment of how well they understood how to write a PDR matched what you found about their ability to write the new very detailed PDR? In compliance actions were there cases, and if so what percentage of cases, where a compliance review was sought that was disenabled by insufficient or inadequate documentation on PDRs?

MR. SMITH: First of all, the results of the SSOP evaluation have not been finalized or published yet. There were some trends that we were made aware of earlier that we made sure that information got into the HACCP training.

I am not aware, other than a brand new employee, of anyone who has not received SSOP training. You can never say 100 percent, but I think we are 99.999 percent. I am not aware if they have not.

Now, there were different types of training with the SSOP. Again, the GS-8 and above received the full three day training because they had responsibility not only for pre-operational but operational sanitation, whereas the GS-7, they rotate through pre-operational sanitation so they

received one day of training and then their responsibilities are on line. That is why there was a difference.

I believe that it is the difference in the one day, the GS-7 training and documentation technique and understanding why we are doing what we are doing. I agree that there are differences and that we are working on that through the work unit meetings.

One of the major reasons we have made the decision that anybody who is trained in HACCP needs to receive the full HACCP training is that that emphasis then goes to the population that is going to be performing HACCP verification, which is GS-8 and above.

One of the reasons why, as Mark said, it will take us quite a bit longer period to train GS-7s is because, one, they don't have responsibilities right now and so we need to determine, one, how do you get 3,000 people off the line to train them -- that is quite a task in and of itself -- and keep that line staffed while you are doing that.

Two, if you don't have direct application to use the skill once you have trained it, is it worth training until you do have that application? I think that is all wrapped up in the pilot.

There are a number of reasons compliance officers can go into a plant and determine with the district manager. Compliance officers do not make that determination in the

plant. The district manager makes that determination of whether we go forward. Compliance officers build a case file.

I don't know if there are percentages where the documentation was not sufficient because it was ineligible. If there are, there are very few cases like that. I think it is more that we look for the linkage that I talked about that you document.

I have said this numerous times in SSOPs, so I am not saying anything new here. You have to document when you would make a system determination that, one, you have regulatory compliance. Two, you have to document in ongoing places bases that the plant did not execute its plan, and, three, and critically important whether you are talking SSOPs or HACCP, is they are failing to implement and execute their corrective and preventive actions.

I can't tell you how many times that that decision is based on the fact that the plant said they were going to do something to correct and prevent it from reoccurring, and it doesn't happen. That is basically the determination that it is made on. Now, you can always say something is not legible or something is not documented right. If we find that, we correct it.

MS. NESTOR: So not a high percentage of actions that do not go forward because inspectors aren't linking?

MR. SMITH: Not that I'm aware of, and I've been involved in a lot of them.

MR. BILLY: Down at the end of the table? I cannot see your name. Sorry.

MS. FORD: My name is Ginger Ford, and I'm with Choctaw Maid. I had a question regarding the non-compliance record.

How is this going to relate to regulations that do not apply to HACCP and food safety; more specifically, for instance, your moisture procedure rotations? If you violate that, how are you going to document this if there are no PDRs?

MR. SMITH: If you turn to Page 29 --

MR. BILLY: Which document?

MR. SMITH: -- of Attachment 5400.5, if you go to Line 7 you will see the relevant section page of establishing a procedure plan that has HACCP, SSOP or Other. Moisture absorption or moisture control would be documented under Other.

Line 8 is ISP Code. There is an ISP procedure that moisture retention comes under, and that would be the procedure it would be documented under. If there was a non-compliance, C would be marked as Product. My guess would be that the economic adulteration block would be marked for the non-compliance trend indicator.

MS. FORD: You would determine it adulteration just because RPMs were not set right on the chiller? This is an example that I can think of off the top of my head.

MR. SMITH: Again, hopefully we teach our people what is known for a fact and reasonable to assume. If RPM is off in and by itself, I hope we're not making moisture control determinations based on that alone, but if RPM is off that indicates either we are having excessive pickup -- one of the possibilities could be excessive pickup, and it might be a trigger to investigate further. That would be written in the description of the non-compliance under Block 10.

Again, the plant defines in their moisture control procedure, and it has been awhile since I have done that, but again the plant defines where they are going to operate their moisture control, their RPMs at and their drip line speed at, the end result being that you have moisture pickup that meets the regulatory requirements.

If you are not executing the plan and one of the critical features is RPMs, that is something the inspector would focus on to make the determination.

MS. FORD: When will the new regulatory updates be out, the changes, the regulations?

MR. SMITH: Do you mean on moisture control?

MS. FORD: No, sir.

MR. SMITH: On HACCP?

MS. FORD: A part of the Federal Register said that you all would re-evaluate regulations and update.

MS. STOLFA: We are re-evaluating our regulations on a continuous basis. We have made a commitment to do first the review and re-evaluation of those regulations that are most directly related to the HACCP regulations themselves, so we are sort of looking at the food safety side of our regulatory requirements first and slowly but surely moving into food safety performance standards.

It takes us forever to get even the smallest regulation out, so I can't be either specific or highly hopeful about how rapidly such a change might be made, but I want to assure you that we are doing it as rapidly and as systematically as we can.

MR. BILLY: What are we working on now, just to give them some sense of what is in the works?

MS. STOLFA: Well, the principal task is for HACCP consistency. We are in the comment and analysis period for the sanitation performance standard. We have a series of product category performance standards that we need to do in order to get rid of some of the command and control features of the current regulations and make it possible for people to meet food safety performance standards without doing things exactly the way they used to in the past.

We have a sort of different series of these are non-food safety regulations that get brought up by various processes. We have some things going on that are brought up because members of the public are particularly concerned about them, but our focus right now is on the food safety performance standards to sort of flush out and provide the substance to the HACCP system.

MR. REYNOLDS: Bryan Reynolds with Gol-Pak Corporation.

Under the training that the inspectors are getting right now, they are being told that they are inspecting for processes and not particular products, right? There are nine different processes that have been explained.

My question is this. Are there any provisions, and I spoke with a couple ladies earlier, about retraining inspectors at a later date, some refresher training?

We have a plant that will not go under HACCP until 1999. However, our inspectors the last two weeks just went through the HACCP training. If they don't have to use this for a year, has the Agency considered retraining of inspectors in case they forget what they have been taught because we are talking about just in time?

The way the 5000.1 directive reads, there is a statement under Initial Plan Development that HACCP plans for each of its products. Now, if they forget between now

and then that they are talking about processes and not one individual product, they may expect us to have 800 HACCP plans instead of nine, 15 or whatever it takes. Has the Agency thought about how they are going to retrain and refresh these folks?

MR. SMITH: Again, obviously I don't know whether your plant is part of a patrol. Our plans are to train people so they can utilize this right away. Obviously there must have been a misinterpretation then if you are not starting until 1999 that your plant was under the big plant implementation.

If you run into that situation, you need to contact your district manager so we can make sure that the folks in that situation -- it would be very beneficial for them to go back through because that is the whole concept of just in time training. You train somebody so they can use the skill right away.

If they can't utilize the skill for a year, then definitely we would probably be looking at retraining. Hopefully we didn't have that many instances of that occurring.

MR. REYNOLDS: One other question. You spoke about pre-shipment verification, and you had the folks up here indicating their individual jobs. Maybe it is just me, but it was my impression that you were actually adding a

separate step past the one of verification that the HACCP plan regulation calls for, somebody to look over everything else after somebody else has already verified and the monitoring has been done before you ship product.

Let me give you an example. A lot of companies I am sure have seen both. If you are in a situation where you are producing a product and it is going straight from the production line to a truck to be shipped, are we expected to hold that product even if it is going to an outside facility that we control for storage purposes because we do not have enough freezer space? Are we expected to have all the paperwork reviewed before that truck can leave the lot?

MR. SMITH: What the regulation says is prior to shipping product the establishments shall review the records associated with the production of that product, document it in accordance with the section to assure completeness, including the determination that all critical limits were made and, if appropriate, corrective actions were taken, including the proper disposition of product.

Where practical, this review shall be conducted, dated and signed by an individual who did not produce the records and preferably by someone trained in accordance with 417(r) training requirements.

No, that does not mean that you have to stage everything. I'm sure there are a number of continuous

operations where the prior to shipping review can be a continuous activity just like monitoring and verification.

MR. REYNOLDS: But it does have to be done before the product can go to an outside storage facility? Say we have a freezer across town that is not on the lot because we don't have enough space on our premises. We have to verify that paperwork before that product can leave our lot to go across town to a storage facility?

MR. SMITH: Again, I think it is your HACCP plan. You need to define what you are going to do. If you are going to do that, that is a critical importance of the plant awareness process so inspectors know. If it's an unexpected facility, then we may have to find other ways to verify, including the use of compliance personnel or something.

It depends on what you're doing and how you're doing it and is that storage or is that the first part of in distribution. All those things factor in. We're not going to make those determinations. You are.

You have to determine how you are going to meet this particular requirement, and then that should be explained through the plant awareness process. I can't emphasize enough the plant awareness process, specifically for questions just like this.

MR. REYNOLDS: Thanks.

MR. BILLY: Kim?

MS. RICE: Kim Rice, the American Meat Institute. On the pre-shipment verification, it has been indicated through the training that you better have a really good reason not to have three people doing the pre-shipment verification. At the training for the industry facilitators, that is how it was presented.

It is my understanding from reading the regulation that where practical, it allows you to have two people doing it, and it also allows for it to be combined, or are you expecting to see three signatures, one for monitoring, one for verification and one for pre-shipment?

MR. SMITH: The regulation defines it as where practical. If it is not practical, we will follow the regulation, as Pat said. We are not putting any new requirements in. That would be a new requirement.

What you need to be convinced is you do not have a conflict of interest problem between the person doing the verifying and pre-shipment review. That is a question that I think would have to be answered by everybody involved. If you have answered that, you know, for your situation, that is fine.

MS. RICE: One more question back on that. Can you do verification and record review at the same time then?

Let's say you are in a continuous process, and the only way to review your records is as you make the product.

You have your verifier who goes there four times a day. Can they do record review and the verification task at the same time? Is that acceptable?

MR. BILLY: You go ahead, and then I want to make a general observation.

MR. SMITH: Again, I think it is hard because I will keep coming back to we have 6,500 plants out there. There are 6,500 different ways of doing it. I cannot say one way or the other if all your verification activity insures that those critical limits were met and the monitoring activity was met.

The reason for doing this is to determine that all critical limits were met and, if appropriate, corrective actions were taken, including disposition of the product. That must be done before that product goes out if there is more to that verification activity than the person who is just verifying the critical limit or monitoring activity was met.

That is why I am saying it is different in each plant. You tell us how you are going to do it. We sit down, and we determine and get it explained in the plant awareness process. We have taught our people if they have questions about that they are to call their supervisor or the Technical Center and not act immediately unless something is extremely obvious that is going to result in

unsafe product. Otherwise they are to call their supervisor or Tech Center, and we will provide guidance on a case by case basis because again you are dealing with 6,500 different plant.

MS. RICE: I just want to bring up that it is being stressed in the training, at least the training that we sat through, that it is three separate people.

MR. SMITH: We will review that with the training center.

MR. BILLY: I would like to make a general observation. We here in the Agency have practiced for several decades the approach of prescribing a very specific approach. We are working very hard not to do that. It should be obvious, I hope, and if it is not it will become more obvious to people.

This is a good example where we want to absolutely stick to the rule and provide flexibility. It is not going to be perfect. If we're doing that, we should fix that. If we start to get different interpretations as we implement HACCP and the deadline passes, we need to deal with those.

This is a process that is underway. Not only is HACCP a process, but this is a process. We are going to work real hard to come out at the other end of this looking and functioning differently in terms of being flexible to allow variation in what is in the end a plant's HACCP

program that they need to really answer the question about what works best for them and what checks and balances they want in their program. We need to get to the point where we can turn it back that way.

Rosemary?

MS. MUCKLOW: This is a policy question for you, Tom and, depending on your answer, a practical question for Bill in terms of training.

There are a number of those 3,000 plants that are due to come in 1999 who have indicated that they may want for a variety of reasons to implement during calendar year 1998. The first question for you is what is the policy of the Agency in providing inspection under its new HACCP system to any of those plants that come in, and when those plants request that is that an irrevocable request? That means they cannot switch back once having got there.

Then the question to Bill is what are you going to do about training the people in those facilities? What sort of time line are people talking about and so on?

MR. BILLY: First, as a matter of policy we are going to allow early participation or shift to HACCP. To accomplish that, we have drafted that and have under review a Federal Register notice that will not only announce that, but it will lay out the procedures that will have to be followed to make that work. It will be a first come/first

served basis.

It will be accomplished by a plant notifying us. The notice will spell out the specifics of how that will be done. It should be obvious that the logistics of getting the training done as plants line up in the queue and we schedule the training is going to be an enormous undertaking. I will let our folks comment more about that. We have designed this in a way where we have the flexibility to do that and intend to do that. There will be an opportunity for plants to come under early.

In terms of reversing, in reviewing the matter with our attorneys we will, upon early entry into HACCP, enter into a contractual arrangement with the plant that will make it clear that they have agreed to participate, to follow the HACCP regulations. We do not intend to provide an opportunity at that point to shift back. Once you make the shift to HACCP, you are under HACCP.

I suppose in the end that could get sorted out in some Court somewhere, but that is our intent.

MS. MUCKLOW: When will the Federal Register notice be out?

MR. BILLY: Where does it stand?

MS. STOLFA: Shortly.

MR. BILLY: In the next few days.

MR. DANILSON: Dean Danilson, IBP.

Bill, conducting a hazard analysis in a HACCP plan has become a very difficult task and much more difficult when we are trying to blend the science along with regulatory oversight and follow the decision rules to come to whether you have a CCP or not.

The question is when we get into the inspector awareness or plant awareness activity and the plant has made through the hazard analysis process a decision that a particular process step is not a CCP and the inspector and/or circuit supervisor believe that it is, what is going to happen and who is going to be the ultimate referee on that?

MR. SMITH: That is a good question. What we are training people to do is we do not do hazard analysis. We haven't trained our people to do hazard analysis, so they should not be determining whether something is a CCP or not.

If they have questions of that nature, they are being instructed to call the Technical Center, lay out the specifics and their concerns. If they cannot get an answer, one, not to be concerned, or, two, it needs more information, they will be directed accordingly.

If the Technical Center cannot make that determination, then they will be calling our policy or public health officials here in Washington, and a determination will be made there, or it may necessitate

somebody going on site to look at it.

In the meantime, you have done your hazard analysis. You have validated your plan. You are producing safe product. Therefore, we are not taking a regulatory action to hold up operations while that process is going on with the exception that if something is extremely obvious.

You know, I keep using ridiculous examples to make the point, but I will go back to if somebody comes in and says I am cooking frankfurters to 90 degrees Fahrenheit instantaneously to control hysteria and staph and all of those, I think anybody in this room can make the determination of what we are dealing with there, but that is on a critical limit.

If you are making a product under the fully cooked-keep refrigerated, you would expect to see a kill step in there, so the obvious things. If it is not obvious or they just do not like something, they have been trained to go through their supervisor or their Technical Center.

MR. DANILSON: Thank you. While I am up here, a couple more questions if I may, along the lines of I am going to term it the now required CCP for zero tolerance fecal on beef and pork carcasses on poultry.

In your analysis or feedback, is the standard carcass AQL that we currently use, that is currently used in the beef and pork industry, going to be an acceptable

monitoring point for zero tolerance CCP?

MR. SMITH: I would say that the Federal Register notice makes the final point of postmortem inspection, which is final rail. Again, that is totally up to you. I do not know how you can monitor zero tolerance at the final rail after the fact, but again that is up to each individual plant.

MR. DANILSON: I do not know if that gets me where I wanted to go, but I will hit that one later.

My third question is in your hazard analysis --

MR. BILLY: Whoa. Let's settle this. What else is there? What else do you want to ask?

MR. DANILSON: Well, if I utilize the carcass AQL as my monitoring point for zero tolerance, which has been an established practice prior to January 26, and all of a sudden it is January 26, I want to know. Is it still going to be an acceptable monitoring practice for carcass dressing, carcass presentation?

MR. SMITH: Again, if that is where you are determining that you have met zero tolerance and your critical limit is zero at that point, you would determine then if you found it.

My guess is we are talking about in the cooler right after the carcasses have received cooling?

MR. DANILSON: Right.

MR. SMITH: You have your critical limit, and then you are going to initiate actions in 417.3. That would be a logical situation.

In the poultry arena it is very specific that it is prior to the chiller. With the red meat, like you say, we have typically done that. We have always emphasized our zero tolerance policies at any point after that final rail where we find fecal material. We would have a deviation and would expect the piece of the 417.3 to kick in at that point.

MR. DANILSON: Let me understand what you just said. You said any time after that point? I believe the November 28 notice said prior to postmortem inspection. What are we talking here in terms of --

MR. SMITH: I think there is a clarifying in the Federal Register notice that talks about the final rail where it is to be met, so you would not want to have it anywhere after that point then. That is consistent with what we are doing today.

MR. DANILSON: The third question that I have, and I am only going to have two more, is in your hazard analysis you make reference to GMPs that bring you to a decision that you do not have a CCP, but it is part of your HACCP plan and part of your HACCP analysis. To give you an example, control of refrigeration temperatures in a cooler, if that

was the case.

Do those GMPs then and the associated records of those GMPs become part of the records associated with your HACCP plan?

MS. STOLFA: We need to get around to something that seems to me to be sorely lacking. We need to be looking at the specific requirements of Part 417. We are not talking theoretical HACCP anymore. We are talking a set of regulatory requirements that are all contained in Part 417.

Now, in Part 417 there is no mention of good manufacturing practices. There is a requirement in Part 417 that a hazard analysis be performed to identify all the food safety hazards that are reasonably likely to occur. For each food safety hazard that is reasonably likely to occur, there must be at least one critical control point.

Now, if you want to do other things or you want to do more things or you want to do multiple critical control points that is not prohibited, but the regulatory requirement is that for each food safety hazard identified as reasonably likely to occur there has to be one CCP in your HACCP plan. You can cut that a lot of different ways, but that is what the regulatory requirement is.

MR. DANILSON: Final question. In making this paradigm shift from old inspection activities to the new

inspection activities, in the past if a slaughter plant were to have received a dirty meat letter it, of course, would have generated activity in the regional or the district or the areas and there would have been plant activities, although you would not necessarily have had a plant withholding of operations.

The way I interpret the actions that we have discussed today as far as shipping of adulterated product is the old dirty meat letter would constitute an automatic HACCP plan failure and subsequent actions against that plant?

MR. SMITH: Again, if we are finding fecal material, I think you have to assign cause. If you can assign that cause back, it says something about the HACCP plan because we just said it is zero after the final wash.

MR. DANILSON: Thank you.

MS. HURLBERT: Alice Hurlbert, National Turkey Foundation.

We have talked about the in plant inspectors will not make a determination on a hazard analysis as to what is adequate and what is not.

What type of training will the people have who will actually be called to consult on this when the inspector has questions? Will the people in the Technical Center receive training beyond what is going on right now?

If so, will that be done prior to the January 26 date?

MR. SMITH: Again, I think when a question comes in, yes, we have a continuing program for training. The entire Technical Center has received the regulatory HACCP.

MS. HURLBERT: It is ongoing then?

MR. SMITH: It is ongoing. Hazard analysis comes down to applying good science and policy, so what I will say there is we are not training people to be HACCP experts. We are training them to make scientific based regulatory decisions. We need them to have that expertise.

If they don't have that expertise at the Technical Center, that's why I said we will come to our policy and public health officials who have the background in science and policy to help us make those determinations.

DR. MINA: Let me add one more comment to this issue. We discussed this issue. When I say we, particularly the deputy administrators or public health and science policy field operation. We will take a collective approach and a team approach to resolving those scientific and technical issues. If they cannot be addressed at the technical center, that will come to Washington. We will take an in-depth look at it and give you a response.

MR. BILLY: Joe?

MR. POCIUS: Thank you, Tom. Joe Pocius with Wampler Foods. My questions these days are not very

esoteric. They are pretty nuts and bolts.

For Bill, when you are talking about Procedure 01 and 02 I believe as well, you are saying that the inspectors will go around, they will look at records, they might take some samples, measure some data, etc., etc. My question has to do with the measuring of the data, and I will give you an example in taking temperatures.

In the past it had been a practice if you had a 2,000 pound tank of meat, the inspector might find one piece within there, maybe a pound or less than a pound, put a thermometer in there, see what it said and pass or fail 2,000 pounds of product on less than a pound of meat.

We have changed that now so that we are taking multiple measurements within a tank to get a better representation of what that product really is. We have written that, and that is what we do.

When the inspector goes out to measure, it is a matter of apples to apples and oranges to oranges. Will they be required then to measure temperatures the way we do in order to make an assessment of whether we have met a critical limit, for instance?

MR. SMITH: Inspectors will monitor that you are carrying out your plan or verify that you are monitoring your verification activity.

MR. POCIUS: Correct. Right.

MR. SMITH: Again, I think we have to say that you set that critical limit so that every ounce of meat meets that temperature requirement. Am I right?

I mean, let me say this. If I have a smokehouse full of product or chill tank full of product and the critical limit is 150 and they put it in there and they find 145, I am just saying --

MR. POCIUS: Well, let's talk about on the cooler side.

MR. SMITH: I am just saying a critical limit is set for that purpose, and all product must meet that critical limit by definition.

MR. POCIUS: If we are talking about a terminal step, I might agree with you.

MR. SMITH: Okay.

MR. POCIUS: I am talking on the cooling side now. A tank of meat is going to vary. We know it is going to vary. Everyone knows. Everyone in this room knows that it varies, depending on how and where you probe. You can use a 36 inch probe to get the center of the tank. You can use a six inch probe to take the top. You can do things to find out exactly what that product is and where it is at.

If you just take one piece of meat, or, worse yet, and not that this happens anymore, but it has in the past. If an inspector gets down on his knees and sticks a six inch

probe through a drain hole because that is where he wants to do it and then passes or fails 2,000 pounds of meat based on that, it doesn't represent that product.

We have gone and used a statistical approach to this. I just want to be assured that when we do that, when we have gone through the trouble of doing it, will the inspectors also be required to do it as well?

MR. SMITH: You have to take into account and follow what you're doing. That is one of the things they are doing is verifying your monitoring and your verification activity.

I will say again that once you set a critical limit to control food safety hazard, it is expected that every ounce and pound of meat meet that requirement. That is why I am having a little trouble with this analogy here.

MR. BILLY: I would assume, though, that Joe would have validation data, including scientific studies, that show that that one piece of meat, notwithstanding the fact that it is not at the required temperature, is not allowing the growth of pathogens to the point --

MR. POCIUS: Sure.

MR. BILLY: -- they would have a problem with the salmonella standard or other requirements that exist.

MR. POCIUS: Yes. In fact, for what we are talking about we have done that. We have found the

citations and whatnot.

MR. SMITH: See, this is why I think we need to look at calibration. We are talking about a chilling tank where you want that product delivered at that temperature. There shouldn't be, or maybe there should be. I don't know. When the product exits and a critical limit determination is going to be made, then each and every piece should uniformly meet that standard. That is where calibration is so important in pump and circulation and those types of things.

MR. POCIUS: One other observation going back to the Q&As that are to be developed and sent out, Q&As and any other applicable documents. I wonder if you might consider putting those on your electronic reading room on the Internet? It makes it a lot easier for all of us to get at without having to wait for announcements and mail and whatnot.

MR. SMITH: There is no reason that cannot be done. Let me again state this Q&A process. We are trying to minimize Q&As because the policy has been laid out to you today. Unless there is something very wrong with the policy, and we need to identify that today, we are not looking to change anything.

Now, a number of times facilitators will ask questions about training delivery and what does that mean, but the policy hasn't changed. It's a how to thing that

they want clarification on. I do not see that as major that we are going to send to the world because one facilitator out of 120 might have that question, so we will answer that person's question.

Saying that, I am not seeing a lot of change or numbers of big Q&A lists. I am not aware that we have those now. Of course, the people that set policy is with OPPD, Pat Stolfa's group, so we always run through back by them.

There is a process they define for setting policy. I think we have to recognize the difference between interpretations, questions about how I do something from the facilitator and then is there something wrong with the policy that has to get fixed or have a question.

I want to make sure that we understand that because I can tell you now that we probably have 60 questions from facilitators, and we have probably answered 60 questions one on one with these people not to set policy, but to help them interpret a particular question that they had. I see that as feedback and not questions and answers. We will not be putting those things out. Anything that would impact on what you are doing of course we would get out there.

MR. MIRTSCHING: I am Warren Mirtsching with Monfort. The question goes back to one of Dean Danilson's with IBP's questions. He asked about final rail versus

final wash.

Bill, I guess I got confused when you answered him because I heard you say final wash. Is that correct? The inspection after the final wash?

MR. SMITH: I was confused. It was the final rail.

MR. MIRTSCHING: The final rail. Okay.

Secondly, during the training that the inspectors are receiving has there been a clear definition defined of what is repetitive?

MR. SMITH: As far as a magic number, no. I will keep reiterating and we have asked all the associations in fact to help us with this, and we keep saying it publicly. There is no magic number.

What is critical in this process is there is a regulatory requirement to be met that is not being met on an ongoing basis. There is a requirement for the plant to address that in whether it is HACCP, SSOP or whatever plan that is not being met.

Critically important in this determination, if you are looking at your PDRs and inspectors are documenting on an ongoing basis this is a regulatory requirement that is not being met, that your plan says you will do this and it is not being met and that you gave me this corrective and preventive action and it either failed or you did not

execute it, that is a pretty clear indication that we have a serious repetitive problem.

No, there is no magic number, but if you in your review of your PDRs are seeing those, and I'll say it again, failures to meet a regulatory requirement on an ongoing basis, failure to implement and execute those things in your plan to meet those regulatory requirements and underscored with 50 exclamation points that you are not implementing or executing the corrective and preventive actions and determining if they are effective and eliminating the problem, then there is where we have a repetitive problem that we will focus on, and that is what we are training our people on.

MR. MIRTSCHING: Thank you.

MR. BILLY: Felicia?

MS. NESTOR: Felicia Nestor, Government Accountability Project.

Currently FSIS can mandate that if there is fecal contamination that the plant trim it, as opposed to spray it off. Will that continue under HACCP?

MS. STOLFA: I think we made a modification in the applicability of the relevant directive for HACCP plants to provide more flexibility in the means which livestock plants in particular can use to remove fecal material. I have to look up the directive.

I believe, and I am looking up the references, the way we are going to go about making the appropriate changes to get our non-regulatory requirements consistent with HACCP implementation is that directives that don't need to apply or perhaps don't need to apply in HACCP plants can be left to apply only in other places. We can make modifications in those directives in terms of their applicability in HACCP plans. My directive --

MR. BILLY: What document are you in and what page?

MS. STOLFA: We are in the 5000. We are in the references to the 5000 and the cancellations and other changes that we are making in order to make HACCP consistently applicable with other requirements that we have. What we have done in this case is we have --

MR. BILLY: What page is that, Pat?

MS. STOLFA: This is Page 4 at the beginning of the 5000.

The Agency is also limiting the application of the following FSIS directives to establishments that are not subject to the HACCP system regulations, and there follows a list of the directives which do not any more apply in HACCP establishments, including directives that have to do with how fecal contamination may be removed in livestock plants.

MS. NESTOR: I have a question about what

repetitive means. I am not sure if now is the time to ask it as a follow up to someone's question or whether I should wait for enforcement this afternoon.

MR. BILLY: I would suggest you wait.

MS. NESTOR: Okay.

MR. BILLY: We are going to get into that.

Caroline?

MS. SMITH-DEWAAL: I am glad Felicia asked her question because this is not my question. It is a follow up to Felicia's.

What data does the Department have to show that alternative methods of removing fecal contamination are as effective as trimming for eliminating the risks of E. coli 015787?

MS. STOLFA: I think that the data that we assembled when we determined that we could permit these alternative methods in certain circumstances supported very well their effectiveness.

The decision that we made was that there would be a size limitation on the area to which these particular techniques could be applied, but there was not any particular reason that would undermine the data that was assembled to support their use in the first place.

MS. SMITH-DEWAAL: Is that data available for public review?

MS. STOLFA: The data was part of a public process that led to that decision.

MS. SMITH-DEWAAL: What decision are we referring to, the steam vacuum decision?

MS. STOLFA: The steam vacuum decision was part of that.

MS. SMITH-DEWAAL: Okay. I was part of that discussion, and I do not recall this. I will check with you later.

My specific question to you is can you clarify the extent to which evisceration will be considered a critical control point?

Let me just give you some background. I am sorry. I am Caroline Smith-DeWaal, Director of Food Safety for CSPI. I don't think I identified myself.

From a consumer standpoint, I don't think there is a great understanding about how HACCP works. All we know is that we promised it is going to deliver safer products. We don't really understand how HACCP could work in a slaughter environment unless evisceration and the potential for fecal spillage as part of that process is considered a critical control point with appropriate monitoring, which actually is frequently done today by USDA inspectors, but also by identifying carcasses which may be potentially contaminated. What is the Department's view on that at this point?

MS. STOLFA: First of all, I think you are asking the wrong person because we do not determine the critical control points. There might be a lot of different answers among the people in this room who would be deciding what they thought were the appropriate critical control points for microbial contamination. I guess we don't really have a view on that.

What we are concerned about is that the requirements of the regulation are met. The regulation says if you have a food safety hazard that is reasonably likely to exist, you have to have one or more CCPs to deal with it. There might be a lot of different ways that that gets done.

MS. SMITH-DEWAAL: Okay. I have two questions, though. You said earlier today that you cannot just reference GMPs like sanitary slaughter practices and also that multiple CCPs are anticipated rather than just one.

Our concern is that you could take a process, for example irradiation, which promises a three to four log reduction in hazard and instead of cleaning fecal contamination off of carcasses you could simply irradiate it and sell sterilized filth to consumers. Is that what USDA intends by not looking at the issue of evisceration as a critical control point?

MR. BILLY: No.

MS. SMITH-DEWAAL: Thank you. I would hope not.

How are you going to deal with this? Are you just going to let every plant do whatever they want?

If Bill Smith goes into a plant and they say well, we have our critical control point and we are irradiating the filth at the end of the line, what are you going to do?

MR. BILLY: I think we have zero tolerances.

MS. SMITH-DEWAAL: Yes, but she just said they can decide whatever they want to do to remove that filth.

MR. BILLY: They have to meet the zero tolerance.

MS. STOLFA: They have to meet the zero tolerance requirement. We will still perform our verifications, which we set.

MS. SMITH-DEWAAL: I am still not clear on this. Maybe you could somehow write it up as part of your Q&As that come out of this meeting or something. This is very critical point from the standpoint of consumers understanding how HACCP is going to work to provide a safer product. Thank you.

MR. BILLY: Okay. That is a good idea.

Dane?

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association.

A footnote to the earlier discussion that Joe Pocius initiated on chilling. Bill used an example of a critical control point on cooking, which is a kill step.

Just kind of a warning flag. We have struggled with temperature control over and over, especially chilling. There is no critical temperature which divides safety from non-safety in that one.

I urge the Agency to think about how you are going to handle those kinds of things because you are going to find all kinds of things showing up in HACCP plans that people did not count on having to live with as an absolute number.

If you are cooking product and you are counting on that to eliminate pathogens, if you say 155 for 15 seconds and it is 14 seconds, I am sorry. That is a deviation. The product does not go anywhere. Forty versus 40½ versus 39½? That is going to be a problem you are going to have to deal with. It is going to be out there.

MR. BILLY: I assume you mean we.

MR. BERNARD: All of us. Absolutely.

MR. BILLY: I assume that the HACCP plans will anticipate that possibility and lay out in exquisite detail corrective action strategies for dealing with it.

MR. BERNARD: Those of us who have been teaching HACCP have tried to urge those kinds of things, Mr. Billy, but I can't guarantee that there is going to be in the industry 100 percent compliance.

The discussion on record review, if I could. At

the end of that discussion when it kind of went away, I was still a little concerned about where we were. I will try to go back to one of those meetings that we had in the back of the cafeteria where the subject first came up. I think everybody that was in the room that day agreed that the objective of the record review was to assure that product which was getting into the trade was in compliance with the HACCP plan.

That being the case, what I think I heard today confirms what I thought the objective was at that time is that there is no set way to do that. There is great concern because of the way the industry has evolved in direct off line shipments, etc.

Those are going to have to be accommodated for, and the industry is going to have to figure out a way to get that done within the framework of the rule, but we would hope that the Agency appreciates that if we have a storage facility that is still under our control and the product is still under our control that the record review can be done effectively before it leaves our control so that if remediation is necessary we still have the opportunity to do that.

That I think is what I heard, and I see heads going this way to indicate that there is some flexibility in interpreting that.

MS. STOLFA: I remember that meeting, and it occurs to me that we certainly need to do a policy notice of this one, as we somewhat anticipated. We will do that, and we did contemplate trying to figure out ways to accommodate the different kinds of practices that were in place now.

We invited people to come forward with suggestions. I don't know that we got a whole lot, but we just sort of theorized some at the time of that particular meeting, including the one that you talked about where there was an off premise facility that was under the control of the same corporation, and to try to find a way that that final verification could be performed. I think we indicated a willingness to do so.

I do need to be very clear, however, in 417.5(c) that the requirement to do this is absolute. There are two sentences in 417.5(c). The first one sets out the requirement. It is the second sentence where the modifier "where practical" appears, and the second sentence is about the qualifications of the person who does it.

Where practical does not mean you have a choice about whether or not this is a regulatory requirement. You have some choice about the qualifications of the person who would do it.

MR. BILLY: Yes?

MR. OLIVER: Earl Oliver with Smithfield Packing.

With this new concept of food safety inspection, along with the industry's role in the HACCP program and the sessions that I have attended and what has happened here today, there seem to be a lot and lot and lot of questions. There is going to be a lot of discussions and perhaps misunderstandings about how this is going to come in place or come about.

I don't want to paint a picture of doom and gloom, but I feel sure that there is a group of people that are going to be very, very busy come January 27, and that is the compliance officers.

What I would like to know is how many does the FSIS have in place and how quickly can they be distributed among the area or from one facility to another to get things going if a withholding procedure was performed?

MR. BILLY: Fair enough. We are going to get into that a fair amount this afternoon, so if you do not mind I would just like to defer your question. We will address it this afternoon.

MR. OLIVER: So I am ahead of you, right?

MR. BILLY: A little bit ahead. The simple answer to your question is we have plenty of compliance officers.

MS. MUCKLOW: Some of us would say too many.

MR. BILLY: I know some of you would.

Elizabeth?

MS. DAHL: Elizabeth Dahl with Center for Science in the Public Interest. I have a question about the slides or the overheads that were up earlier.

There was a flow chart that talked about when non-compliance was found, and then the next thing that the FSIS does is ask whether there was a system failure, and that is what determines whether there is a withholding action or not.

Can you give an example? Can you explain what a system failure is and how you determine what it is and maybe give some examples?

MR. SMITH: A system failure would be, in my mind, if we had a critical limit. Let's say we had a cooking, a kill step, on let's say we had hams. The plant has set 160 degrees instantaneous for that kill step. That is validated in their HACCP plan that that is effective. They monitor that on each smokehouse.

Let's say that the product came out at 158 or, and we will make it more ridiculous, 150 instantaneous and that the monitor did not pick that up and, therefore, allowed the product to move into the chilling.

In the plant verification, one of their duties was determining that the monitoring was done correctly, and they did not pick that up. On the prior to shipment review, the person doing that signed off on all monitoring and

verification activity.

If the inspector found that, there would be a system determination that the system did not work because, one, the critical limit was not met and by definition that was put in place in the case of a kill step to eliminate a hazard. It has not accomplished that, and the plant did not take responsibility to act upon that. In that case, we would have by definition the shipping of adulterated product.

MR. BILLY: Bill, suppose in your example that that happened, the 150 degrees, but someone in the plant quality control picked that up and took action against that batch and then triggered their correction actions approach that would deal with that.

MR. SMITH: Yes.

MR. BILLY: There was a failure. It may not have even been noted, but now they have taken action to deal with that batch of product. What else would we expect them to do, and how would we react?

MR. SMITH: Okay. In that situation, let's say they found it on the plant review. We would be very interested that all four parts of 417.3 were carried out -- that the product had adequate disposition, that the critical control point was back under control, something was put in place to prevent it from reoccurring and that no adulterated

product was shipped.

In that case, we would not have a system determination if the system is working. We would document a non-compliance, though, for monitoring because monitoring was not carried out. That is the difference. You have non-compliance. If it is not a system failure, then you document the monitoring non-compliance, but you would make a determination the system was working,

MS. DAHL: So a system failure means there were multiple failures of monitoring steps along the way --

MR. SMITH: Right.

MS. DAHL: -- so there is the possibility the product could have already been shipped out there by the time the system failure determination is made, and it may be too late to deal with the withholding action?

MR. SMITH: If product is in the marketplace that is determined to be adulterated, we would either detain or seize or talk about recall. That would be an automatic in that if you made a system determination that product had gotten out, yes, then we would detain, seize or recall.

Again, it is a very important point that you brought up. It is a barrier process. That's what I said earlier. The monitoring is there as the initial barrier. The verification is the second barrier. The pre-shipment review is the third barrier.

If it gets through those three barriers, we do have a serious problem, but I suspect it would be more the one that Tom brought up that either the verification effort picks it up or the pre-shipment review would pick it up.

MR. BILLY: Kim?

MR. SMITH: If not, we will be there.

MS. RICE: Kim Rice, American Meat Institute.

Bill, can you clarify something for me? Through the training, it is my understanding that if you don't do the pre-shipment review it is an automatic system failure. Is that correct?

MR. SMITH: We are saying that if the product is out and the pre-shipment was not done that we cannot make the determination. You go back to the language in the reg that says you must make a determination. The plant must make a determination that all critical limits were met.

If we can't make that determination that all the critical limits were met, we cannot allow the marks of inspection to be applied to that product.

MS. RICE: But if the records indicate that monitoring and verification were done and any corrective actions that were needed were taken, all that is not there is the signature on pre-shipment.

MR. SMITH: Again, we are getting into, yes, did somebody forget to sign something, but the plant can

demonstrate that they did it. Of course, that would not be a system problem. The problem is again we need to know and it is the plant's responsibility to make sure that occurs and document that.

MS. RICE: I understand that. I am not questioning whether we should do it or not.

MR. SMITH: Well, the scenario was if there was not a pre-shipment done. If there is not a pre-shipment done, then I cannot make a determination that critical limits were met. Therefore, I cannot allow the marks of inspection to be applied.

Now, if it was done and somebody just forgot to initial it, that is a record keeping non-compliance. It is not a system determination. Again, the record keeping requirements about initialing and signing are in the reg. If we have a repetitive history of that then we might make that determination down the road.

MS. RICE: Okay. I have another question about the non-compliance since we seem to be in verification now.

If you have a Process 01 procedure, the inspector is doing a Process 01, and he finds two issues let's say in SSOPs, a monitoring issue and a corrective action issue, he automatically goes into 02?

MR. SMITH: Okay. We didn't explain that. That is a good point.

The Process 01 and 02 would be in the HACCP mode. The SSOP, we stated, was --

MS. RICE: Okay. Let's go with HACCP. He is doing an 01.

MR. SMITH: In an 01 they would document on a non-compliance record and provide you notice that there was non-compliance. We are telling everybody right now and it is in the directive. They will automatically switch into an 02 mode and track that specific production all the way through pre-shipment to insure that corrective action or whatever took place.

MS. RICE: But my reading of the directive and through the training is they would only mark one non-compliance trend indicator.

MR. SMITH: Right. Right. At a time. You mark one at a time.

MS. RICE: So if it was monitoring and corrective action, which one would get marked? That is my question. There is obviously a hierarchy of the four trend indicators.

MR. SMITH: I don't think there is a hierarchy. If you have multiple things, usually we have been teaching our people verification.

Corrective action, you are right, is extremely important to us, but I think that would be a verification. If we have corrective action failures, that is extremely

important. We would mark corrective action. If we had multiple things, usually that comes under the broad category of verification.

MS. RICE: Okay.

MR. BILLY: Felicia?

MS. NESTOR: Felicia Nestor, Government Accountability Project.

Pat, the research that you were talking about that justified going from trimming fecal to washing fecal, did that include a study that specifically demonstrates that when you wash fecal contamination with a high pressure nozzle such as in a carcass washer or head wash cabinet that that is not going to push the contaminants into the tissue and that will then not be detected with an E. coli sampling or a salmonella sampling technique? Is there any specific research on that?

MS. STOLFA: All of the literature on the subject was reviewed, including the very limited number of studies that addressed that topic specifically as part of making this decision. The specific research that was the core of that big body of data that caused us to change focused not on hoses as a means of removing fecal contamination, but on steam vacuum. That was the significant change that was made at that time.

As part of that and as part of the Federal

Register notice we eventually published that announced that, even though it wasn't a regulation we wanted everybody to know that we were making that change. We reviewed all of the literature on that subject. I happen to know there are only a small number of studies that actually addressed that specific point, but they were included in the literature review.

MR. BILLY: Right.

MS. NESTOR: I have seen PDRs where head wash or carcass wash which is something like 450 psi jams contaminants into the tissues. It is my understanding of steam vac is that you don't have that sort of high pressure, and it is actually pulling stuff off the carcass, right? It does not seem that the steam vac research would apply.

MS. STOLFA: As a part of making the decision to permit that technique, we reviewed all the literature on the subject and put that literature review summary in the Federal Register notice.

MR. BILLY: You need to get the reference and go back and read the literature summary. It is all of the different studies of different techniques, including the one you are referring to.

Dennis?

MR. JOHNSON: Thank you, Tom. Dennis Johnson, Olsson, Frank & Weeda.

Upon reviewing some of the training materials, I remember the example, and, Bill, I want to confirm that this is where you are all still at.

If during a smokehouse the monitoring schedule adopted is every 20 minutes they will go and check the readout and if an inspector is tasked with an 01 procedure and goes during those 20 minute intervals before the plant has even had a chance to look at the monitoring and notices that the temperature was too low, hangs around for a few minutes, the plant monitoring person comes, detects the deficiency deviation, takes corrective action, lets everyone know, it still is going to be written up on the non-compliance record even though the system was working perfectly?

MR. SMITH: Not in that situation where the system is working because it was between monitoring and they could document and take action.

This has become a big question, so let's just say if you have a continuous system or a recording system that you can document and then make a determination and the plant finds it and deals with it, there is no problem with that at all, no non-conformance.

If we have a non-continuous system, and let's use the ridiculous example that somebody is going to take a temperature every hour and that is the only check. Our

people in their monitoring or verification activity finds between in that hour that the temperature was not met and then when the monitor comes back in an hour that the product is being met, we still know that we had product that was not meeting the critical limit at that time, and we are going to put people on notice in that case that we did have a monitoring failure.

Now, the plant cannot verify that because they have no recording and no continuous way of doing that. Hopefully we are not controlling our critical limits that way where we have a non-continuous process. We can either determine through conveyor speed or we are charting the heat of the wet/dry bulb or the dry bulb, that we have backup systems.

If we don't have a backup system and it is non-continuous and our people determine that the critical limit was not met, as long as we will react on those and then we would write that up as a monitoring non-conformance and switch automatically into the 02, or if we are performing an 02 verify all the way through the 417.3 that corrective action was carried out.

MR. JOHNSON: Keeping with my example, let's say the monitoring person missed that deviation. The verification person comes in and determines oops, we missed. He stops it and goes ahead with corrective action.

MR. SMITH: Okay.

MR. JOHNSON: Is that going to be written up on an --

MR. SMITH: Yes, sir, because HACCP 417.2 says you need to define your monitoring and your frequency. Again, we're talking about critical limits here. We're not talking about food safety hazards being controlled by critical limits.

Yes, it's good that the plant catches it, and, yes, we would expect that they initiate 417.3 or if the verifier can determine that the critical limit was met, we still expect an action to be taken to insure that monitoring activity as defined in that program is being carried out.

MR. JOHNSON: Okay.

MR. BILLY: I think part of that scenario you laid out is what is true about the pathogens you are trying to address. What information does the plant have that would inform us about that deviation? It needs to turn on that type of information for the future.

It could end up that both the plant and we would learn that whatever their frequency of monitoring was, it was not frequent enough given the circumstances. I would see a HACCP plan being modified. That is the potential outcome. It depends on the circumstances.

MR. CORDREY: Tom Cordrey, Purdue Farms. My

question is about a CCP.

If you have a CCP where you are trying to reduce bacteria -- not trying to eliminate, but trying to reduce it -- and you have a systems failure, why do you consider that adulterated product?

MS. STOLFA: I think it depends on whether or not it gets out.

MR. CORDREY: Let's say it does get out.

MS. STOLFA: The determinations about whether or not product is adulterated rests on establishments being able to demonstrate to us that the systems that permit us to make a conclusion that it is not adulterated worked. We do not want to go around chasing after product all the time anymore.

This is based on an approach of systems which establishments have the responsibility for designing and maintaining in accordance with regulatory requirements.

MR. CORDREY: If you get your system back in place, why would that product that gets out be adulterated if you are still trying to reduce the bacteria and not eliminate it?

DR. MINA: Are you talking salmonella or E. coli?

MR. CORDREY: It does not make any difference.

DR. MINA: It does.

MR. CORDREY: E. coli.

MR. BILLY: E. coli 015787?

MR. CORDREY: I am sorry?

DR. MINA: Are you talking about 015787?

MR. CORDREY: Generic E. coli.

DR. MINA: Okay. That product is not adulterated. I think the purpose of the testing is to assure process control.

MR. CORDREY: But you have said, though, if that product gets out it is adulterated if you fail your CCP critical control limits.

MS. STOLFA: That is because of the enforcement theory. The process was not in control.

DR. MINA: If the process is not in control, that product is adulterated. You lost control of the process. The system failed.

MR. CORDREY: But you first said that was not adulterated, and then you changed your mind.

DR. MINA: What do you mean, changed your mind?

MR. CORDREY: Well, you just said it was not adulterated.

DR. MINA: It was.

MR. CORDREY: You said it was not, and then you just changed your mind.

DR. MINA: It is adulterated once you ship product that was as a result of a failure of a system. That is what

Bill Smith was talking about. If it passes all three interventions, the monitoring, the verification, the prior to shipment, and none of these people caught this product, then that is a failure in the system.

MR. CORDREY: Okay. You have fixed your process. You have taken your corrective action and fixed your process, but you have not held the product.

MR. SMITH: Again, you established in your hazard analysis what a critical control point would be, so you have said in your plan -- not us; your plan -- that this is a critical control point that is going to control, reduce or eliminate that hazard.

Therefore, if you have not controlled, reduced or eliminated that hazard with the things you have in place to do that, then you are not carrying out your plan.

MR. CORDREY: But you have carried out your plan as far as a system.

MR. BILLY: No. Let me approach this a different way. Why did you establish that critical limit for that particular --

MR. CORDREY: Because it is proven that they reduced the bacteria.

MR. BILLY: Why did you reduce the bacteria? What hazard are you addressing?

MR. CORDREY: Let's say it is E. coli, for

example.

MR. BILLY: Okay.

MR. CORDREY: Let's say you had two or three critical control points, and each one is reducing the bacteria more.

MR. BILLY: Why would you establish a critical control point for generic E. coli?

MR. CORDREY: I used that for an example. You could do it for total plate count or whatever.

MR. BILLY: Why? I am trying to get to the public health reason. Why are you trying to reduce whatever it is in your example?

MR. CORDREY: I am trying to reduce the bacteria.

MR. BILLY: Because if it is not reduced there is a public health concern?

MR. CORDREY: Because on the raw products, I don't have a way to eliminate it.

MR. BILLY: Whatever your example is, why are you reducing that? What is your public health objective? What are you trying to accomplish?

MR. CORDREY: I am trying to get the bacteria levels down to a better level.

MR. BILLY: Okay.

MR. CORDREY: I am not going to get them down to zero, so I am not going to have an adulterated product out

there either.

MR. BILLY: So failure to do that means what? If you are trying to get that down because you are going to have a better, safer product, whatever your words are, and you fail to do that --

MR. CORDREY: But I have not.

MR. BILLY: You have not. You failed to reduce the number down to whatever your limit is, but you have not failed to -- I cannot follow your logic.

MR. CORDREY: We have had HACCP in place for over a year.

MR. BILLY: Yes.

MR. CORDREY: We have reduced the bacteria using critical control points that reduce the bacteria, but we necessarily haven't held the product in that short period of time it gets out. We have not considered it adulterated. We are doing what everybody wants to do.

We are reducing the bacteria. That is what this is all about. Then this new thing gets thrown into the system. You have to hold the product.

MR. BILLY: Hold the product.

MR. CORDREY: I do not understand it.

MR. BILLY: I cannot follow that.

MR. SMITH: Again, I am not sure. All I am saying is 417.6 lays out what determines to be an inadequate

system. The plan in operation and the establishment fails to take corrective action. That is where we are at a loss here.

You have defined a critical limit. You said you were going to monitor it and verify it. You are saying you have monitored and verified and determined the critical limit is not met, but you do not want to enact a regulatory requirement defined in 417.3 which is disposition of your product that did not meet a critical limit.

MR. CORDREY: I fixed the process, but not necessarily went back to the last good sample and held that product. It is already in another form now. I cannot go back and put it back in the form you want it in. I cannot rework it.

MR. SMITH: Again, I think we have to focus on 417.3 that talks about there is a responsibility to deal with product disposition in that case no matter what form it is in. You have to make the determination, and that is where we said process and this, that and the other. You have to make the determination whether you are dealing with an unsafe product or not.

MR. CORDREY: Is there a definition of adulterated somewhere?

MR. BILLY: In the Act.

MS. STOLFA: In the Act, but not in the HACCP

regulations.

MR. CORDREY: In the law. Would the example I gave come under that example?

MR. BILLY: Yes, it could, depending on the pathogens, what is on the product. Yes.

MR. CORDREY: Let's say salmonella.

MR. BILLY: It may contain a poisonous or deleterious substance that would be injurious to health.

You need to go back. There is a section in the preamble to the final rule that talks about this very issue, I think, if I am following you now.

We can show you up here the basis for the determination that when the system fails that we are not able to verify that the product isn't adulterated. You need to see that section and re-read that. Maybe we can come back to it after lunch.

MR. CORDREY: What I think this is going to lead to is a lot less CCPs diluting the whole program down to I don't think it's where we want to be.

MR. BILLY: I think this may be a point to break. Let's be back here at 1:15 p.m.

(Whereupon, at 12:09 p.m. the meeting was recessed, to reconvene at 1:15 p.m. this same day, Tuesday, December 16, 1997.)

A F T E R N O O N S E S S I O N

1:37 p.m.

MR. BILLY: I guess we will get started again.

A couple messages. One, at our desk out here they are delivering messages, so if you are expecting a message you should check out with the desk periodically. They will try to find you if they can, but this is a pretty good sized group.

Secondly, I need to remind you again to state your name and your affiliation as part of the process so the reporter can get that information correctly.

When we finished off, we were talking about an example that was raised in terms of disposition of the product and whether the product was adulterated or not. With the assistance of my colleagues, I am going to take a stab at addressing this a little further.

In the HACCP regulation, the regulation is written around the premise that if you carry out the requirements in the regulation then we are in a position to determine that your product is not adulterated, i.e, it is suitable to bear the mark and to flow into commerce.

If you have a system failure, and I am not talking about what caused that, but if it is as we described this morning a system failure that we have determined, then it to us triggers a point where we are not able to accomplish what

I just described, i.e., determine that your product is not producing adulterated product. In that instance, we will take action based on the HACCP regulation regarding the failure of your system.

We had mixed into that discussion disposition of product related to it containing some kind of bacteria. It makes a difference in what you are talking about, but if it is a pathogen for which there is not an established performance standard and you have set a limit that is based on available technology that reduces and controls but does not eliminate that pathogen and then you have a system failure, if there is not an established standard for that pathogen that has been violated then the disposition of that product in question is different than the decision about your system.

Your system has failed, and we will take action regarding your system. The product in question, absent either a zero tolerance or another specific tolerance for that pathogen, would be taken into account in terms of what happens with regard to that product.

We expect that plants, as they encounter situations where they have a breakdown in their system and, among other things, as the rule requires they have to make a decision about the disposition of the product, would take into account the public health significance of what is true

about that lot in question and whether there are established performance standards or not and any other relevant information as part of that decision process that the plant would carry out. We would look at that area as well as part of our verification activity.

Other than getting into a very specific series of examples about specific pathogens and specific situations, I think that hopefully will make it clear that we are talking about different things here. One is about disposition of product. Another one is about a system failure and how we will react to that.

Pat, I do not know if you want to add anything. Pat?

MS. STOLFA: I do not think I have anything to add. I think that sets a distinction.

MR. BILLY: Bill? Anyone?

DR. MINA: I think it is clear to me. I do not know if anybody else has a question.

MR. BILLY: It is hard because we are making a transition to a systems basis. In some instances, disposition of product is important as well. HACCP is designed to address that, and we expect it will. We will verify that it does as part of the decision process in those circumstances where you have a system failure.

MS. MUCKLOW: Could I ask a very obvious question?

MR. BILLY: Yes.

MS. MUCKLOW: Rosemary Mucklow, National Meat Association.

I assume that you are going to run parallel systems for the 314 plants that are under HACCP and all the rest of the industry over the next three years. Is that a correct statement?

I mean, you are still running the rest of the industry on traditional inspection and PBIS and so on and the 314, so you are going to have a lot of duplicative things. You are going to have directives that are not phased out for the old system, but are phased out for the new and so on. That is going to be a challenging time to keep everybody on the right page.

MR. BILLY: Maybe I should take up knitting or something.

MS. MUCKLOW: I recommend it. It helps to keep your sanity under difficult conditions.

MR. BILLY: Fair enough. Are there any burning questions left over from this morning before we get into the next topics?

MR. HUSKEY: Excuse me.

MR. BILLY: Yes?

MR. HUSKEY: I just have one.

MR. BILLY: You bet.

MR. HUSKEY: Len Huskey with Swift & Company.

I had read that the inspector could trigger an action to withhold inspection leading to compliance coming in and so forth, but I think Bill this morning indicated that only the IIC would take such action and not a GS-8, for example. Could we get some clarification on that?

MR. SMITH: It would be the inspector in charge. Of course, any documentation from any of the people doing the HACCP verification would play a part in that determination, but the inspector in charge will make the decision to withhold the marks.

MR. BILLY: All right. Now we want to move on to the next agenda item, which is Salmonella Performance Standards. Charlie Gioglio is going to lead the discussion on this. We had some handout materials. Hopefully you have all availed yourselves of those. Charlie will use that material as the basis for his presentation.

MR. GIOGLIO: Thank you, Mr. Billy.

I guess what I would like to do this afternoon is to review what the salmonella performance standards are and then to walk through, so to speak, the two papers that were available outside. They look like this. If you have not picked them up, you can pick them up.

One is titled Issue Paper, Strategy for Salmonella Testing, and the other is Issue Paper, Public Release of

Salmonella Testing Results. I would like to go through those two issues in some detail, and then I guess we can field some questions on that.

Just by way of background and to sort of contrast the salmonella performance standards a little bit with the E. coli testing, the rule in fact, the HACCP pathogen reduction rule, establishes performance standards for raw meat and poultry products, both carcasses and ground product, for salmonella.

The salmonella standards, the performance standards, actually complement the process control performance standards for fecal contamination and the E. coli testing programs that are done by the plants. The salmonella samples are collected by inspection personnel and tested in the FSIS labs. We will be tracking the data on those and so forth.

The reasons that salmonella was selected were all spelled out in the preamble to the final rule, but that salmonella was the most common cause of food borne illness, bacterial cause of food borne illness. The data indicates that it lives in the intestinal tract of mammals and birds for food purposes.

Current methodologies can recover salmonella from meat and poultry products easily, and maybe most important interventions aimed at reducing fecal contamination and

other sources of salmonella should be effective or are effective against other pathogens.

The performance standards themselves provide incentives for producers of the raw meat and poultry products to reduce the prevalence of salmonella on those products. In addition to that, they provide a substantive basis for the Agency and for in fact establishments to judge the effectiveness of their HACCP plans.

Just to sort of review, and this is maybe small for those of us in the back. Just to review, that slide actually lists the salmonella performance standards that were promulgated with the final rule. The first column in the class of product. The second is actually expressed in terms of percentages, but those are the performance standards. The next two columns there tell us the N or the number of samples that we will collect and will be a sample set.

The last column is the maximum number of positives. By way of contrasting here, I would say the salmonella testing is positive or negative. We are not, as in the case of E. coli, enumerating the number of bugs, so to speak, but is it a positive test or a negative.

When we go on to talk about this in the jargon I guess we have developed, we use the term sample set. The sample set is that N, that number of samples, whether it is

53 or 51 or 82, whatever the case may be, on the given product.

The sample collection methodology that our inspectors will be using in the federal plants are the same as the plants are using for the E. coli testing. We are sponging cattle, hogs and now turkeys, and we are doing a whole bird rinse on the chickens.

For ground product, and I would say here with the salmonella performance standards, ground product also have had standards set for them, we take a 25 gram sample. That is what is tested at the laboratory.

Getting into now a little bit of detail on the testing program as we have designed it, the testing program, and some of you can go back and remember what all was spoken about in the preamble, is broken down into two parts. There is a pre-implementation part, samples collected before the HACCP rule would become effective at a given establishment, and the compliance part. The compliance part is what we will be starting in January, you know, as of January 27 for the largest establishments.

I will discuss a little bit more later on the pre-implementation part of it, but I would like to go into first the compliance phase or the compliance part of the testing program and give you a little bit more detail there.

That program will be broken down into three

components. We are going to have product specific targeting component or a sampling frame, as it will, in the jargon or the pool from which establishments will be drawn to sample. We have termed that as product specific targeting.

The plants that will be placed in that pool initially are those plants that are producing products whose performance standards are in double digits, so specifically we are talking about ground turkey, ground chicken and chicken. The performance standards, if you will, from the slide that Ron had up a minute or so ago are in what we are saying double digits. In other words, for broilers it was 20 percent, for ground chicken 44.6, and ground turkey 44.9. That product is in the product specific.

The next component is plant specific target, plants from which we have taken a set of samples, and I should say that plants that are in the product specific pool will all be sampled, will all have a sample set scheduled for that plant for the inspectors to collect. Any plant that would fail that first set would then go into a plant specific targeting pool or targeted frame. Any plants in that frame will also be scheduled for a sample set.

The next component then will be all the plants by default that are not in either of those two frames, and that will simply be a random pool or a random sampling frame which over time we will get to each of the plants, but they

will be selected at random. It will not be a targeted thing that we will initiate as of the first sample schedules that are going to be generated in actually inspectors will start inspecting February 1 or 2.

As I said, we will be starting the sampling for practical reason in February, the first week in February. You can expect to have samples collected at your plants. If you're in one of the largest establishments, those will be compliance samples. If you operate a small or a smaller or a very small establishment, you could expect that once they are trained, the inspectors, the IICs, will be collecting samples at those establishments to begin the pre-implementation phase at those plants. That will also start at the same time.

The next thing, and I can talk about this in a little more detail, will be the enforcement policy for the salmonella testing program enforcing the performance standards. I guess the best way that we can think about this is sort of self-contained. It was all spelled out in the final rule what the enforcement for the salmonella testing program will be.

If a first sample set is scheduled, and that might be a targeted sample set, or it may have been a random sample set. If the performance standard is not met, we will have that data in headquarters. Headquarters will notify

the district manager. The district manager will be in communication with the establishment and the IIC of that plant, and the deficiency in this case will be documented on an NR that Bill had spoken about earlier, the non-compliance report.

The district manager will inform the establishment that they are required to take appropriate action to meet the standard. At that point, we will go ahead and schedule that plant for a second set of samples. Normally that may be within about a 60 day period. There is some flexibility in that based on recommendations from the district manager. It may be a little bit sooner, or it may be a little bit later, but you can rest assured that we will be scheduling a second sample set for those plants. That is what I spoke about earlier, that targeted frame.

If a second sample set performance standard is not met, again the same notification would go to the district manager, and the district manager will be in communication with the establishment citing very specifically the regulatory requirement for the establishment to reassess its HACCP plan for that product and take corrective action. Again, that will be documented on an NR.

Again, the plant will be scheduled for then the third sample set. Based on the timing of that, again we will be in concert with the district manager, and that

district manager will take certain factors into consideration in making the recommendation to headquarters of how soon to schedule that particular establishment for the next set of samples.

If then the third is not met -- we will schedule the next set, and if that third set is not met -- the district manager would inform the plant now both orally and by certified letter that they have failed to maintain an adequate HACCP plan for that product, citing the appropriate parts of Part 417 of the regulation, the HACCP rule. That again would be documented on a certified letter. It would be documented also on a non-compliance report.

Inspection service for that product will then be suspended and will remain so until the establishment submits to the FSIS administrator or his or her designee written assurances on the actions taken to correct the HACCP system. Again, that is in accordance with Part 310.25(b)(3). That language is fairly specific there of what will happen about the suspension and then the written assurances from the establishment.

At that point, the administrator will assemble the appropriate mix of technical and policy people to evaluate what the establishment submitted before that suspension would be released and whatever appropriate follow up enforcement action would need to take place.

On the good side of all this, and there is a positive side, as the plant, and this is whether in targeting or the random. If a plant passes a sample set, they will simply be placed back in the random sampling pool.

I would like also to give you some highlights on the other issue paper that was outside on the table, that one titled Public Release of Salmonella Testing Results. Jennifer is here. If anybody needs or would like a copy of that paper, she will be coming around and can provide you with a copy of that.

I am not an expert in the FOIA or the Freedom of Information Act area, but I would like to walk you through the paper. We will deal with whatever questions come up. Possibly somebody else on the panel may want to jump in if I don't know a particular answer.

Obviously FSIS understands our obligation to release the data which we own. I would like to go back, though, and make two other points. The goal of the salmonella testing program is to verify that establishments are meeting performance standards with the ultimate goal of reducing the incidence of enteric pathogens in products nationwide.

The performance standards measure performance over time. Therefore, multiple samples are needed to make compliance determinations. I spoke a little bit earlier

about sample sets and completed sample sets. One individual salmonella result is not meaningful then in that context, but the sample set does tell us something.

Our policy then is that any of the pre-implementation data, and pre-implementation data is all the data that was collected from June 1, 1997, to the date that the establishment is required to come under the HACCP rules. That is for small, large or very small establishments.

At this point, we do not intend to use any of the data that we had collected from June 1 until the end of January next year for any purpose for the large plants. We did not collect as much data as originally intended, and that is for a wide variety of reasons. At first we thought that data may be useful in actually developing target strategies, but the Agency decided against that approach.

We will collect pre-implementation data, as I had stated earlier, in the small and very small plants starting now with the sample schedules coming up in February. The Agency will determine the appropriate use and disclosure of the data as the testing proceeds. Requests for pre-implementation data will be addressed under the Freedom of Information Act on a case by case basis.

Compliance data, that which we are going to start now in the largest plants, will be sent on the completion of

a sample set, will be sent to the individual establishments. Those establishments will be sent their own testing data. Just to restate that, the individual establishment will be sent their own data on completed sets.

Plant specific data will be made available in response to Freedom of Information Act requests and will be provided again in completed sample sets. At this point, the Agency has no plans to post the salmonella data at the Web site, and though we believe that we should publish an annual report on the testing program, the details, content and format of which will be decided.

That is all I have as far as a formal presentation.

MR. BILLY: Okay. We would like to open it up for questions.

MR. BYRD: Ken Byrd with Pilgrim Pride.

The week before last in the FSIS school at College Station, a concern was voiced on this issue that it would be beneficial for plants to have the salmonella data as it was collected so if a trend was developing, the plant could take some corrective action before the whole series was out.

It was my understanding in a teleconference with Bill, and correct me if I misunderstood, but it was my understanding that a system was being worked on to address that issue where data would be fed back to the plant on a

test by test basis rather than waiting until the entire set was completed. Did I misunderstand, or has something changed?

MR. SMITH: I think Jeanne Axtel is going to be able to answer that question because she answered it at the picture teleconference.

MS. AXTEL: This is Jeanne Axtel. At the time of the picture teleconference a couple of weeks ago when the question was raised, the response that we gave at that time is that the Agency's thinking earlier had been that we would release the sample results at the time the sampling results were available back to the plant from which it was collected rather than waiting until the end of the complete sample set.

We also indicated during the teleconference that the matter was still under discussion within the Agency and in fact that the final determination had not been made. What is being discussed at this time is the final Agency position with respect to the distribution of salmonella results.

MR. BYRD: Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: Rosemary Mucklow, National Meat Association. I have two questions.

Somebody back here would like to know when will we

receive the standards for whole body turkeys? They were afraid to ask the question. They know I'm not a shy person, so they thought they'd ask me.

MS. STOLFA: After we have had a chance to complete our analysis of the turkey baseline on which they would be based. We haven't completed that yet.

MS. MUCKLOW: Do you want to give us an approximate time, Pat?

MS. STOLFA: Well, I am trying to get it done as fast as possible. I was hoping within the next month or so.

MS. MUCKLOW: Thank you, Pat.

MR. BILLY: Are you going to convey that message back to whoever --

MS. MUCKLOW: Yes. I'll write it on this and send the piece of paper over.

The other question I have is my own question, which is never as erudite as the ones I get fed, and that is are our international trading partners going to be subjected to the same standard here and the information made as available as it is for domestic companies? That is a policy issue, Mr. Billy.

MR. BILLY: Thank you.

MS. MUCKLOW: I know you are glad I came all this way.

MR. BILLY: I am. In terms of being exposed to

the same policy and requirements, the answer in terms of complying with the HACCP and pathogen reduction regulation is required for all countries that ship product to us. If countries don't ship product to us, then they obviously can have their own requirements, whatever they are. We're not in a position to affect that.

Whether a foreign country makes the data available to their public will turn on whether they have a Freedom of Information Act type requirement in that country. Some do, and some don't. Those that do, they vary pretty widely in terms of what is made available and on what basis.

You would actually have to look very specifically at those countries that do have that to figure out what would be required in terms of making that data that they are generating to comply with our regulations for purposes of exporting product to us available to their public.

We will, as an inspection matter, have access to that data and can review that data and consider that data as part of our evaluation of their inspection system. We will have access to it. We will consider that data and their whole testing regime, in fact, as part of our evaluation of their inspection system.

I hope that answers your question.

MS. MUCKLOW: We just want to make sure that what is good for the goose is good for the gander, as my mother

used to say. If you are going to have access to that data, are you then going to make that data available to everybody else like us?

MR. BILLY: If we take possession of that data, then that data is available under the Freedom of Information Act.

MS. MUCKLOW: Are you going to send your emissaries to their country to look at it and not bring it home, or are they going to bring it home?

MR. BILLY: I do not know if we thought that far, but our --

MS. MUCKLOW: I just want to make sure equivalency means what I thought it meant.

MR. BILLY: I understand. We think it is appropriate to have the same basic kind of data and information available to our public, whether from a domestic plant or from a foreign plant.

Caroline?

MS. SMITH-DEWAAL: Caroline Smith-DeWaal, Director of Food Safety for the Center for Science in the Public Interest.

Tom, I have been going back over the final rule, and this said that you were going to have approximately 250 samples per establishment over a one year period for the pre-implementation phase. What happened to that? Why was

it not done? How much was done? Then I have another question.

MR. BILLY: It took us longer than we anticipated to get all of our systems in place to handle this kind of volume of product being both sampled at the plants and shipped. We ran into special shipping problems, one of which was a strike, if you remember, as well as procedural and handling problems in the labs themselves.

We anticipated starting before early June, but in fact it took us until early June to complete the process of not only getting all the systems in place, but then doing the audits to know that we are producing consistent, reliable results.

At that point when we knew that, we then actually started the pre-implementation sampling. During the almost six months now, there are some plants where there are complete sets. There are some plants where they are not complete. What we have said is that information is available to the plants, and we will make that information available under the Freedom of Information to anyone that requests it.

Because of the fact that there are some where they are complete and some where they are not, we want to be able to cover that data with appropriate information to explain what it represents and what it does not represent. That is

our plan as part of responding to requests for that data.

It is also the reason why we are starting a little earlier in terms of the pre-implementation testing for the small plants and then eventually the very small plants because in some of those plants, particularly as they get quite small, they are not even slaughtering, for example, every day. Completion of a set could take a significant amount of time. We are factoring all that into our plans.

We have the capacity now to handle the volume of samples which we estimate to be when we are fully in all the sampling about 250,000 samples annually. We have established the capacity to handle that volume of sample collection and analysis. That is what happened. That is what we were able to complete. We are following the procedures that were laid out.

MS. SMITH-DEWAAL: And just a point of clarification. The sample size is the same size as what is published for the final rule for compliance implementation? It is not the 250,000? Okay.

My second question is I understood from a meeting we had I believe last September that the publication of salmonella test data on the Internet was actually a legal requirement for FSIS because it is information in the public domain that you believe you will receive multiple requests for.

What has happened to that determination, and if in fact you find you are receiving multiple requests for it when can we expect it to appear in the reading?

MR. BILLY: We will follow the requirements in the amended Freedom of Information Act that provide for making data available electronically in response to multiple requests. We will be driven by the facts, the specific experience we have in terms of those kinds of requests and respond accordingly.

MS. SMITH-DEWAAL: Is that on a plant by plant basis so some plants will be subject to disclosure in the reading room and some will not, or is that going to be handled based on the data request in terms of the category of data?

MR. BILLY: It will be based on the request for the data.

Felicia?

MS. NESTOR: Felicia Nestor, Government Accountability Project.

Am I to understand that all of the samples are not to be taken on the same day? Is that correct?

MR. BILLY: Yes.

MR. GIOGLIO: Yes.

MS. NESTOR: They will not be taken on the same day?

MR. GIOGLIO: Normally one sample will be collected per day. You can see some of the sample set sizes are quite large. The normal frequency for collecting samples would be one sample per day.

MS. NESTOR: When you say normal frequency, are you announcing that that is what you will do, so all large plants can expect that they are going to have one sample taken per day?

MR. GIOGLIO: What I am saying is that the instruction that will be given to the inspector will instruct them to pull a sample a day for each day that the plant produces that given product to be tested, whether it is ground beef or chicken or whatever the particular product has to be.

At some point the Agency has some flexibility there. For various reasons we may increase that sampling, but the normal routine sampling will be once per day.

MS. NESTOR: In response to what the gentleman was saying before, if a plant finds that it is starting to get a certain number of samples and it says well, can it petition the Agency to stop taking samples for a little while? No? That is not going to be a factor?

MR. GIOGLIO: No.

MS. NESTOR: Okay. Second question. The technical amendment said that poultry plants can now, if it

is impractical to take their samples post-chill, they can take the sample pre-chill. Is there going to be a requirement that poultry plants make product available for sampling post-chill, or can they construct their facilities in such a way that it is impossible for FSIS to get to the birds post-chill, and they will also have to take it pre-chill?

MR. GIOGLIO: Let me say this. I am not exactly sure technically what they would do or what they could do, but we would not allow a plant to somehow construct something that would preclude the inspector from taking the sample.

If that would happen on a case by case basis, we would, through supervision, establish the appropriate sample collection protocol for that plant.

MS. NESTOR: But right now all samples will be taken post chill in poultry, all salmonella samples?

MR. BILLY: I think there are certain instances where that is not right.

MR. GIOGLIO: Right, in say the hot boning of --

MS. STOLFA: Right.

MR. SMITH: In a hot boning situation or whatever. Again, in those cases we will instruct the inspector with the appropriate sampling protocol. In some cases, it may be a case by case basis or a plant by plant, but that

instruction will be provided to that inspector.

MS. NESTOR: So there are salmonella standards for those situations also?

MR. GIOGLIO: The same salmonella performance standard would apply.

MS. NESTOR: The same salmonella, even though supposedly --

MR. GIOGLIO: It is not a different standard.

MS. NESTOR: Are there not studies that show there are more positives after the chill tank than before the chill tank?

MR. GIOGLIO: I am not aware of that.

MR. BILLY: I have never seen anything like that.

MR. HIBBERT: Good afternoon. Bob Hibbert from McDermott, Will & Emery.

Back in November, with regard to specific salmonella standards, the Agency published a document through something called the direct final rule where it articulated a standard for pork sausage products. As I understand that process, that becomes a rule unless there were what were called adverse comments received, in which case the Agency goes back to traditional rule making.

Some adverse comments were filed. Can we therefore assume that those standards won't be enforced until a rule making process is completed?

MR. BILLY: Yes.

MR. HIBBERT: Thank you.

MR. BILLY: Rosemary, and then down at the end of the table?

MS. MUCKLOW: We have experienced some difficulty knowing what protocols you are practicing in the lab on some other testing. Where can we find or obtain precisely the protocols that you are using, and how can we be assured that we will know when you change those protocols?

DR. MCNAMARA: That is my question. I think most of you know me. I am Dr. McNamara. I am the Director of the Microbiology Division.

The USDA, like FDA, is under no regulation that makes it mandatory for us to publish our laboratory protocols. However, as a courtesy we have always given them out for free upon request. We have been doing that for over 20 years.

To make things even simpler, next spring we are going to publish our laboratory protocols. An announcement will be coming out in the spring as to where you can purchase that. It will now be by purchase, but you will be able to get it through the Government Printing Office, and you can have a complete set of our protocols.

MR. BILLY: How about keeping it up to date?

DR. MCNAMARA: It will be kept up to date on a

regular basis. The initial plans that we have are to probably update it on a yearly basis.

MS. MUCKLOW: Will it be available on your Web page?

DR. MCNAMARA: The plans are to do that, but what we had decided is that because many people are not using the Internet at this time that we would go out with a published version in the spring, and then the idea would be in the future to put it on the Internet. It would be your responsibility to keep up in looking at the Internet site to find any new changes.

MS. MUCKLOW: The people who would be interested in this are probably more computer literate than people who are not interested in this.

DR. MCNAMARA: I am glad to hear this.

MR. BILLY: Are you all set now, Rosemary?

MS. MUCKLOW: Yes.

MR. BILLY: Way down at the end?

MS. WYNN: My name is Janice Wynn with ConAgra Fresh Meats.

What is the procedure that would be followed in the event that a grinder that uses an outside supplier of product fails the performance standard? Would there be tracking by FSIS or compliance back to the supplier then?

MR. GIOGLIO: Let me just start off to say --

DR. MINA: I do not understand the question. Can you repeat the question? I am not too sure I understand what you are trying to say.

MS. WYNN: Okay. An operation grinds ground beef. They get their product from an outside supplier, but the testing is done at the grinding operation for the salmonella performance standard. If they fail the performance standard, is there going to be tracking back to the supplier because probably that is where it came from?

DR. MINA: Normally we won't do that, but in some cases we might. It's on a case by case basis. It depends on the particulars, but not as a matter of routine.

MR. BILLY: It is possible that the supplier plant may have failed. If we happen to be sampling them at that time, we may pick up the problem that they are experiencing that would cause that as a possibility.

Also, if we have that experience and it is pretty clear that one supplier is providing material that is high in salmonella, that would likely trigger a targeted response in terms of that supplier plant, if that is what you are --

MS. WYNN: Thank you.

MR. BILLY: Caroline?

MS. SMITH-DEWAAL: Thank you, Tom. Caroline Smith-DeWaal, Center for Science in the Public Interest. I have some follow up to Rosemary Mucklow's questions.

The first question is you have been challenged over the last year that your testing technology for salmonella, particularly for ground beef, might not be adequately validated, and there was some mention of the fact that perhaps the sponges had an anti-microbial effect.

Could you tell us the status of that challenge to the testing protocols? Do you understand what I am --

DR. MCNAMARA: Let me backtrack a bit for people who have not followed this.

In June of this past year was the IAMFES meeting, the International Association for Milk, Food and Environmental Sanitarians. At this meeting, Kansas State University published some very preliminary, non-validated data which looked at the sponge method that is currently outlined in the rule.

Their preliminary data showed large reductions of bacteria in as little as five minutes and especially over two logs of bacterial reduction in 24 hours. This data was very different than any published data previously. We invited Kansas State researchers to our laboratories to work side by side with us to find out why this data was so different.

What we learned is that the protocol they used did not correspond to the one that is published in the regulations. In the published regulation is the sponging

method as we are currently using it. What KSU did was to sponge their samples mechanically -- was to stomach their samples mechanically -- for about a half an hour.

To stomach a sample means to put it in a device that pulverizes it and just smashes it between iron blades. You can imagine taking a sponge and smashing it for 30 minutes really drives bacteria into those porous surfaces. In the regulation methods, it is only a two minute stomaching.

We presented this material before the National Advisory Committee for Microbial Criteria in Foods, which is a group of micro experts throughout the country who advise USDA, FDA, U.S. Marine Fisheries and the Department of Defense on microbial issues. They reviewed the data and said that yes, these early preliminary data did not follow USDA methods and did not produce the same results as we are getting in our sponge methods. Subsequently, KSU also presented at that meeting follow up data which did support our sponge method, and also other scientists presented data which supported the sponge.

The National Advisory Committee came out with a recommendation stating that the early studies did not reflect the method we were using and that the sponge method is perfectly suitable for process control validation studies such as being used in the reg.

We hope that this clears up any of the confusion that was brought forward.

MS. SMITH-DEWAAL: Thank you for that clarification.

Also, you said in response to Rosemary that you would be publishing your testing protocols. Will that mean that any change in your testing protocols will have to go through notice and comment?

DR. MCNAMARA: No, no, no.

MS. SMITH-DEWAAL: Okay. Fine.

DR. MCNAMARA: Let me back up and make that perfectly clear again.

MS. SMITH-DEWAAL: Thank you.

DR. MCNAMARA: USDA and FSIS give out their laboratory protocols under no regulatory requirement to do so. It is a courtesy. We have been doing that for over 20 years upon request.

The methods that we will be using for salmonella and generic E. coli are no different than those that have already been published in the regulation. What you have is what you will see.

In the spring we will be publishing as a method of getting this information to you in a readable format a new microbiology lab guidebook. It is going to be in two volumes, and it is going to be every assay that we are

currently following; not that you would want to reproduce everything that we are doing because you do not have some of the regulatory requirements we do, but just as again a sharing of information. This will be published. The E. coli testing and the salmonella testing will be no different than what is in the regulation that you are seeing now.

From the National Advisory Committee there was only one request, and that was that we clarify in our regulations that currently the two buffers being used are Butterfield's phosphate diluent and buffered peptone water. Those are the two diluents we recommend, and that will be the only thing that will be clarified. Everything else stands as is.

MR. REYNOLDS: Bryan Reynolds, Gol-Pak Corporation. I have a couple of questions I would like clarified.

The ground product samples that are being pulled, is that before the addition of any spices or any other ingredients? It is straight out of the grinder, right, with nothing else added?

MR. BILLY: In the plants, yes.

MR. REYNOLDS: Okay. Second question. I asked this one last year at the SOP meeting and got a we hadn't considered it answer, so let's see if you have one now.

In hot bone pork operations that make fresh pork

sausage, are we subject to salmonella testing on both the carcass and the ground product or only the ground sausage?

MR. GIOGLIO: Yes.

MR. REYNOLDS: We are?

MR. GIOGLIO: Both performance standards would apply.

MR. REYNOLDS: Both? Okay.

MS. RICE: Kim Rice with the American Meat Institute.

Last year you indicated that in hot boning operations you would focus on the ground product.

MR. GIOGLIO: That is correct.

MR. BILLY: That is right.

MS. RICE: And then back to the question about seasoned versus not seasoned. In hot boning operations, it is virtually impossible to get unseasoned product.

MR. GIOGLIO: To go back, and I guess this answers the other gentleman's question a little bit more fully. We will make every attempt to collect the sample prior to the addition of any seasoning. If it is impossible in a given situation, then we will take a sample that has had seasoning added to it. That is pretty much stated that way in the instruction material to the inspector and so forth.

MR. BILLY: Katie?

MS. HANIGAN: You answered my question already.

MR. BILLY: Okay.

MR. EMERLING: Stan Emerling representing the North American Meat Processors Association.

I would like to come back to the question Ms. Wynn raised about the trace back on the product where you are not a slaughterer, but take product from others and then grind it or handle it in any other way. That has been a point that our Association has raised time and time again without really getting an adequate answer.

We find ourselves in the middle. We in a sense have the possibility of being victimized by errors that occur downstream which we are then held responsible for because we are the closest to the customer.

When you start taking at grinding only the samples on 0157 or salmonella or whatever else you decide to do and then do not make those who deliver the product to us responsible for having sent us product like that, have no obligation whatsoever to inform us if they have even found out that there is a problem with that product because they may test for 0157 and have not even a moral obligation. Maybe they have a moral obligation, but they certainly do not have a legal obligation to withhold that shipment and send either those trimmings or carcass meat forward. It can be full of salmonella. It can be full of 0157 or anything else.

I think that as an agency you are not fulfilling your obligation to all of us in the stream of commerce if you do not address that question. I really have not been able to understand why we have not been able to get some response to it.

Thank you.

DR. MINA: I will respond to that, Stan, a little bit different than my earlier response. I think it is the plant's responsibility to identify through their hazard analysis system.

One of the first things that the plant that is grinding product would look at is supplies of raw product. That is one of the things that the plant would do initially is test the incoming products and make sure they are acceptable according to the plant standard and specification. That is part of the continuous HACCP system. It is incumbent on the plant that is grinding that product to make sure that the supply they receive are acceptable.

MR. EMERLING: Okay. If I may respond to that?

MR. BILLY: Can I add a little bit before you do?

MR. EMERLING: Yes, because that is not answering. It is leaving me in the same place.

MR. BILLY: All of the plants that both slaughter and produce ground product, ground beef as an example, will be sampled according to the approach that Charlie laid out,

the targeting approach, both considering the product, as well as plant performance. As a minimum, they will be in a random pool, so all plants that produce the slaughter and produce ground product will be in that random pool.

In addition to that, where we have a situation where the same plant is both slaughtering and grinding, we have indicated that we are going to tend towards the ground product for sampling purposes, part of the reason being if there is going to be problem, it is more likely to show up there because of the blending of the product.

We are not saying that we will not also sample the carcasses as well. That remains an option available to us, depending on the circumstances.

In the instance where you are a grinder purchasing product from various suppliers, I think that Mark has kind of hit it right on in terms of, one, the responsibility you have as a grinder to address your raw material and whether it can contain materials, hazards, that have to be addressed and either require your suppliers to provide you that information or do testing yourself either of the raw material or the product you are producing.

This matter of being the victim I think has to be addressed as part of the change to the HACCP based system. There is data available. There is not only salmonella data, but there is generic E. coli data available as well.

I hope that all plants, particularly those downstream that are using raw material to produce ground products, will take advantage of that type of information and data in developing their HACCP plants.

MR. EMERLING: With all due respect, I think we need to come into the real world of how people have to operate in the businesses that we are in. For me to expect, and I've seen this written in all your reports, and both Mark and you, Tom, are reiterating the fact that we should have protocols or systems in place that set up HACCP stops.

I can ask my suppliers for guarantees. We're small plants. I doubt whether I can get them because there aren't very many plants you can buy from. If I get turned down by everybody, I'm not going to have any merchandise so you have effectively put me out of business.

They can test as much as they want to test. If I want to test to see if they sent me something, I have to do 100 percent of the product test, and then I have nothing left to produce for product for my customers. Therefore, I have to reorder again and I'm back in the same position. It is not realistic what you're saying.

Now, I can ask for steam pasteurization. I can ask for every type of intervention on that carcass. Maybe that will bring my risk level down, but what you are still doing is you are putting the burden on that part of the

industry which does not have control over how the animal is slaughtered.

Whether or not you are asking for zero tolerance, and that is fine if it is there, but you have not done that with E. coli, and you have not done it as far as 0157. I think you really need to look at that because are you trying to leave the business only in the hands of the biggest companies out there that have all the science and all the technologies, or are you trying to put away the middlemen who are defenseless and don't have the dollars to support or to fight it.

One of the larger companies with a lot of resources went down overnight when you stepped into that action, and that was Hudson Foods. I think you really have to look at this. It doesn't do any good for me to go back to our people and give them the kind of answer that you have just given me, with all respect to what I hear you say, and I understand what you are saying.

MR. BILLY: The only additional thing I wish to say is we are going to hold all plants to the same standards.

MR. WEBB: Neil Webb, WTG Laboratory.

Is there going to be any effort to electronically correlate these data from the carcass samplings and the receipt like Stan is talking where you get samples let's say

of ground beef or ground turkey? Are you going to relate that back to the establishment it came from and look at their protocol and results?

MR. BILLY: Where that is possible, we will look at that in terms of grinders that are using raw material. As I answered a question earlier, if we see that kind of a problem and it is clear it came from a particular source and warrants further examination, then we will use that information to target a slaughter plant or whatever is appropriate there for follow up salmonella testing. We will do that. It is correlating it in that sense.

MR. WEBB: I think the Agency would benefit by that. I think the industry would. I think the industry also has the responsibility to do the same thing.

MR. BILLY: Okay. Other questions, or are we going to move on?

MR. BRICKEY: Keith Brickey with ConAgra Refrigerated. A real quick question.

Have the baseline studies taken into consideration the regional and seasonal differences?

MR. BILLY: Regional?

MR. BRICKEY: And seasonal differences.

DR. MCNAMARA: The baseline studies have always taken into account seasonality. The nationwide baseline programs are conducted over a year period, and they have

taken into account seasonality.

The current studies that we are doing now by the sponge will also have their M&Ms set and their final level for salmonella after a year's data collection so that salmonella is included.

Now, that is different than the product surveys that we do. The product surveys on ground products have been collected for less than a year's period. However, they have been collected for substantially more time than has ever been done in the past.

In studies in the past, as many of you will recall, a survey would be someone going out and collecting 100 samples of a given product and looking for the bacterial levels on that product and considering that a survey. When we did our ground product surveys, those products were expanded to about six months or more of production until we got statistically valid numbers as set by our statisticians in order to set the performance levels that we did.

MR. BILLY: As to your question about regionally, I think we cover regionally through it is a nationwide sampling that is designed to collect materials from plants that produce 99 percent of the domestic supply or the domestic production. We get that regional distribution that way.

MR. BRICKEY: Thanks.

MR. BILLY: All right. We have a break scheduled at 3:00 p.m. I would like to move on to enforcement, so maybe what we could do is break now for about 20 minutes, and then when we come back we will talk about enforcement and any other issues anyone has.

(Whereupon, a short recess was taken.)

MR. BILLY: All right. We are going to get started. The next item on the agenda is the area of enforcement.

I was just looking around the table. Unlike the past public meetings, I do not see the bank of Washington attorneys sitting here.

VOICE 2: They are here.

MR. BILLY: They are here? Okay. I mean at the table and together.

MS. MUCKLOW: They are in their Christmas outfits today.

MR. BILLY: Just teasing.

We wanted to cover this aspect of the new regulation in terms of how we will be enforcing it. To that end, we have several people here that I would like to introduce.

First is Carol Seymour, who is the Assistant Deputy Administrator for Enforcement under Field Operations. Next we have Phil Durfler, who recently came to us from the

Food & Drug Administration. Phil works for Maggie Glavine in the policy area. He is the Assistant Deputy Administrator under Maggie Glavine for Policy, Program Development and Evaluation.

Finally, Dick VanBlargen. Dick is our senior person in terms of the enforcement area, has worked a great deal on the material that is going to be presented, and, as I understand it, he is going to actually make the presentation, so I will turn it over to Dick.

MR. VANBLARGEN: It is good to be here this afternoon.

MR. BILLY: You need to move the mike up pretty close.

MR. VANBLARGEN: I will get a little closer here. Rosemary always claims that I have a booming voice. I will use the mike today, Rosemary, and talk very softly.

MS. MUCKLOW: Speak up. Speak up.

MR. VANBLARGEN: Before I get started, there were some handouts outside, one on the enforcement statement that I am about to give, and the other one is on the rules of practice, the proposed rule. There was a handout out there also. We will be referring to those two issues this afternoon.

MS. MUCKLOW: What does that one look like?

MR. VANBLARGEN: It is one sheet of paper, and it

has on the top Issue Paper, Rules of Practice, Proposed Rule.

MS. MUCKLOW: Okay.

MR. VANBLARGEN: Carol has asked me to provide the statement. She needs to save her voice today. She had a little surgery last week so she needs to save her voice, but she is here to answer questions. I will go ahead and start with the statement, and then we can have questions afterwards.

I want to thank everybody for coming today, and a this point we would like to turn our attention to the topic of enforcement of the HACCP regulations and explain the concepts that underline the approach that FSIS intends to take. The formal remarks will cover about 20 minutes, and then we would be happy to receive any comments or answer your questions.

The conceptual shift embodied in HACCP and which industry must assume as proper accountability and responsibility for its food safety enhances the importance of the effective enforcement program. Last year FSIS introduced sanitation, SSOPs and other components for enforcement that would complement the rule and provide the level of public confidence necessary to accomplish a fundamental shift in the approach to food safety.

We also described how the new organization of FSIS

and the changing roles of inspectors and compliance officers would support effective implementation of the rule and allow both FSIS and the regulated industry to focus on their respective responsibilities for insuring that food is safe.

As we move towards the January, 1998, HACCP implementation date for large plants, it is useful to review these concepts, assess how they have been applied in the past months, and consider what adjustments will be both possible and appropriate as plants implement HACCP.

In a summary of these enforcement concepts, the first new concept to consider is the changing roles that the regulated industry and the inspection and compliance functions of FSIS. While the pathogen reduction and HACCP regulations provide enormous flexibility for the industry to develop and implement innovated measures for producing safe foods, they also impose clear and unequivocable responsibilities for preventing contamination by pathogens and other hazardous substances.

This clearly defined role for the industry, accountability for food safety, was accompanied by a change in the roles of inspectors and compliance officers to verify, inspect industry practices and to take enforcement actions when plants' control systems failed to meet regulatory requirements.

Another concept introduced by the regulations is

the linkage between a plant's ability to control processes and the eligibility of products to bear the marks of inspection. Under traditional inspection, the finding that product is not adulterated and thus eligible for the mark if USDA inspection is based on FSIS inspectors examining products for evidence of contamination. Under the new regulatory framework, this finding will be made based on FSIS concluding that sanitation and process control systems operated by plants are preventing adulteration.

If products are not produced under appropriate control systems as evidenced by the production or distribution of unsafe products or by continuing system failures attributable to the same root cause, FSIS will act to withhold the mark of inspection until plants can assure both corrective and preventative actions are in place and effective.

A third concept that provides for clear understanding of the new enforcement processes is the changing significance of plant actions to address deficiencies that are detected by inspectors or plants. The traditional inspection program was based on the concept that inspectors find deficiencies and plants correct them. This find and fix mentality did little to encourage preventative measures because it created the perception that it was only necessary to remedy the problems that inspectors found.

Under the new system, plants are responsible for finding deficiencies and for using the information they gain when they check their systems to strengthen the preventative process controls. As a result, plant actions to detect and assess deficiencies to determine their causes are viewed as evidence of proper functioning control systems.

FSIS verification includes a review of these actions through observation and records review to determine whether systems are functioning. Thus, as long as plants maintain their systems properly, including detecting, documenting and correcting deficiencies, there is no need for FSIS to take enforcement action.

By contrast, a pattern of the same or similar deficiencies occurring again and again will lead FSIS to conclude that the plant does not have in place the required process controls. This type of deficiency is very serious and leaves the Agency little choice but to withhold the marks of inspection.

A fourth concept has to do with how FSIS uses its resources to hold plants accountable for insuring the safety of foods they produce. The new FSIS organization integrates inspection monitoring resources and enforcement resources into a unified district structure and assures new roles to FSIS compliance officers.

In the past, compliance officers were primarily

responsible for products in distribution channels and generally contacted and inspected plants only when following up on violations that involved product that had already been distributed in commerce.

The new organization enables FSIS to use the training and expertise of compliance officers to assist in plant inspectors in documenting failures of plant control systems and helps to insure appropriate due process when enforcement actions are needed.

A team approach to enforcement actions also helps insure that actions are consistent and fair and that plants receive appropriately documented notices of violation and an opportunity to comply with the regulations. Through close integration of resources, FSIS can respond quickly to situations in which plant operations have been interrupted and determine whether corrections have been effective or whether suspension of inspection is warranted.

A related concept emphasized as we introduced the new regulations last year involves the rights of plants to receive notice of alleged violations and the right to appeal Agency actions. FSIS believes that appeals of legitimate disagreements are both necessary and appropriate.

Plants are encouraged to appeal inspector findings at the earliest point in the process. Some plant officials may dispute findings, but let them go unchallenged until an

enforcement action based on the findings is underway. Similarly, plants may disregard inspector findings which they mistakenly believe are erroneous, allowing needed corrections to be delayed unnecessarily.

Last year we solicited comments and promised to consider revising our supplementary rules of practice. Obviously we have not issued new rules, but we do plan to have a proposal soon. In the meantime, we will continue to apply existing rules and provide actual notice of proceedings and appeal channels as needed when bringing administrative complaints.

In the application of enforcement processes, since January, 1997, FSIS has undertaken a systematic process to enforce requirements for developing sanitation SSOPs, monitoring generic E. coli and assuring compliance with zero fecal tolerance standards. Similar enforcement protocols have also been developed to be applied in the other regulatory context such as preparation of fermented sausages and, as data sets are completed, adherence to salmonella performance standards.

As new regulatory initiatives are developed, these enforcement protocols are likely to become the standard model for FSIS enforcement actions for plant non-compliance. As discussed previously, each model is based upon a clear mandate that establishments implement control systems that

assure food safety by preventing contamination and adulteration.

FSIS inspection tasks and verification assessments are designed to measure how well plants prevent problems. FSIS assesses any problems that do arise in two ways. First, FSIS determines if any action is needed to prevent shipment of adulterated products. Second, FSIS determines whether the plant control systems are adequate to allow continued use of the marks of federal inspection.

FSIS has stressed proper documentation of deficiencies for two reasons; first, so plants have adequate notice and opportunity to comply, and, second, to establish the basis for enforcement measures, if necessary, to address system failures.

Most enforcement actions to date have been effective in addressing plant problems in early stages, and, thus, it has not been necessary for FSIS to intervene to withhold the marks of inspection for any extended period. In many respects, these enforcement actions have been similar to those that have been in place for over 90 years.

Inspectors use authority to retain and condemn contaminated products and reject or tag areas of the plant or pieces of equipment much like they always have. However, the new regulations call for steps that go beyond these product control actions to address plant systems if the

plants are failing to prevent recurring problems.

Although there are numerous variations depending on the particular circumstances, the protocol for enforcement actions includes the following general steps: First, inspectors in charge, IICs, through a non-compliance report provide notice to plants when requirements of the regulations are not being met.

Second, IICs are instructed to notify the plant management officials that the marks of inspection are being withheld from products and to contact the district office. Third, the district office sends a compliance officer to the plant to further document the situation.

It is important to note that at this and any subsequent point in the process, the plant is encouraged to quickly respond to the information that the IIC has provided about non-compliance. We expect a compliance officer should be on site within a few hours and have instructed them to complete their reports as soon as possible.

Our experience to date has shown that these situations are resolved quickly if plants are prepared to expeditiously file any appeals or present any proposed corrective or preventative actions to the district office while this documentation is being completed.

The next in the process is for the district office, in conjunction with headquarters district

enforcement operations, to review the compliance officer's report and any written or oral information submitted by the plant. Typically plants that have reached this point have not fully appreciated the need to be accountable for their process controls and ask FSIS to tell them what to fix.

District offices have provided plants with guidance on what is necessary to avoid a continued suspension of inspection by explaining that the plant should: One, identify the qualitative assessment process the plant used to determine nature and cause of SSOP or other failures. Two, identify what the assessment revealed as the likely cause of the problem; that is, the specific reasons the system failed to prevent any direct product contamination.

Three, specify the actions taken or plan to eliminate the identified causes of sanitation or other process deficiencies. Four, describe specific changes to be made in the plant's SSOP or other control plans. Five, determine the future monitoring activities that the plant will use to insure that the changes are effective.

If plants are successful in addressing these matters, FSIS will issue a notice of suspension held in abeyance. In effect, this notice says that FSIS has concluded that the plant's systems have failed but that the plant has acknowledged the problem and developed a plan to

develop its reoccurrence.

Typically we have held these abeyances for several weeks or months to verify that the proposed corrections and preventative measures are made and are effective. Once the verification occurs, plants are issued a warning letter to close out the file.

District offices will issue a notice of suspension covering all or part of a plant's operation when the plant fails to respond or fails to adequately address the root causes of the non-compliance. At this point, plants may appeal or resubmit proposed action plans.

Although to date none of the actions has progressed beyond this stage, the next step in the enforcement protocol would be a complaint to withdraw inspection. If the plant is making a good faith effort to correct problems, we would wait to file the complaint to withdraw inspection and keep the suspension in place. Otherwise we would proceed with the complaint quickly as soon as we conclude that the matter cannot be resolved without a hearing before an Administrative Law Judge.

The application of concepts during the past few months. Through mid November, 1997, of the total 6,496 plants operating under federal inspection, 6480 plants had established a level of compliance that did not require an FSIS withholding or suspension action. FSIS opened 16 cases

as a result of district office findings that plants had failed to develop or maintain effective SSOP systems.

Five cases were closed with a letter of warning after inspectors verified that the plant had completed corrective action or after the plant voluntarily stopped operations requiring federal inspection. Eleven cases are now pending with suspension of inspection held in abeyance. In none of these cases has it been necessary to file a complaint for withdrawal of inspection.

Numerous other situations are now under review as the compliance and inspection team apply a proactive approach. The proactive approach involves the team assessment of documentation in plants that have begun to accumulate a history of non-compliance. FSIS is encouraging its field managers to openly discuss these situations with plants and to gain commitment to avoid a continued pattern of sanitation and other deficiencies before enforcement actions are necessary.

Record keeping. Before closing these remarks on enforcement, we should turn our attention to another concept introduced last year which concerns the growing importance of truthful and accurate record keeping by meat and poultry plants. Accurate records are necessary for both the plant and inspector.

Plants need records to verify that their control

measures have worked and that their products are safe and wholesome before deciding to ship them in commerce. Inspectors rely upon both hands on observations and review of plant records to assess whether systems are functioning properly.

In the absence of adequate records, we cannot conclude that products are being produced safely, that critical control points are functioning and process standards are being met. Plants that maintain false or deceptive records to avoid inspection oversight are in jeopardy of criminal prosecution. FSIS's enforcement activities now and in the future will give priority to cases involving incomplete or fraudulent records.

In closing, it is essential to stress that none of these enforcement actions is undertaken lightly. They represent an enormous strain on Agency resources and potential market disruptions that affect not only the plant that is under scrutiny, but also their suppliers and customers. However, the alternative of continuing to allow products to be produced without adequate food safety controls would have far more serious consequences.

FSIS is committed to a systematic approach with adequate supervisory overview to insure that there is a nationwide consistency and fairness to both plants and consumers. This process provides plants with notice of

non-compliance that forms the basis for enforcement action, an opportunity to appeal and voice disagreements and time to propose corrective actions before FSIS proceeds with the appropriate enforcement measures.

We hope this discussion has been informative, and we would be happy to hear your comments and answer your questions at this time. Thank you.

MS. SEYMOUR: As Mr. VanBlargen mentioned, there is a flyer on the rules of practice that is available. We do expect that we will have those rules out very soon. A draft of the proposed rules is in clearance process.

One thing that I would like to stress about the rules is that they are a streamlining and consolidation of existing procedural rules that we have been applying. When we did the original of the final rule on HACCP in pathogen reduction, we indicated that we would accept comments on changes to our rules, and we do believe that the comments only directed us toward clarifying the language that we were using and the process that we were using in terms of describing it, not changing it.

You won't expect to see in the new proposal any changes in the procedural steps that we have been applying that Dick mentioned in the remarks and that are outlined in the speech that you have. It will be a proposal, and again we will accept comments. We still are always looking for

things that would make the process work smoother for everybody involved.

MR. BILLY: At this time I would like to open it up to comments or questions.

MS. NESTOR: Felicia Nestor, Government Accountability Project. This is actually Tom Devine's question. I am delivering it because he is not here.

The regulations mention that it is a violation of HACCP to take an action which prohibits or inhibits a company employee from truthfully and accurately disclosing circumstances in a plant.

I am wondering what steps should the plant employee or the FSIS inspector follow when the plant employee is inhibiting in that way, what instructions have been given to inspectors, and is there a requirement in the HACCP plan that the plant address that issue?

MS. SEYMOUR: I am going to assume you are talking about an intentional conspiracy to subvert the record keeping requirements?

MS. NESTOR: Yes.

MS. SEYMOUR: That would be subject to our normal investigatory processes and criminal action.

MS. NESTOR: Is there an instruction to the inspectors? Is that part of the HACCP training?

MS. NESTOR: If the inspectors are involved in a

situation where the plant is subverting them and not allowing them to look at records or hiding records from them, we would see that as impeding the inspection process, and we would expect --

MS. NESTOR: I do not mean that. What I mean is in the training for the inspectors on their HACCP --

MR. VANBLARGEN: Yes, there is.

MS. NESTOR: -- enforcement --

MR. VANBLARGEN: We have instructed our inspectors if they suspect that there is any foul play with regard to record keeping, false record keeping, anything to do with record keeping, they are to immediately notify district enforcement operations.

MS. NESTOR: Okay. Is there any protection for plant employees who would reveal --

MR. VANBLARGEN: You are talking about something in the form of a whistleblower?

MS. NESTOR: Yes.

MR. VANBLARGEN: That does not apply. That is addressed in the preamble of the pathogen reduction.

MS. SEYMOUR: As we have answered before in the same question, we do often have confidential informants, and we do protect the identity of confidential informants to the extent possible.

MS. NESTOR: If an inspector went to the district

office and said that they knew of a case where a plant employee had tipped them off, there is a good chance that that could not be resolved without the employee's identification coming to light.

MS. SEYMOUR: That is right.

MS. NESTOR: So the inspector could not really take any action without jeopardizing that person's job?

MS. SEYMOUR: There are some instances where a confidential informant is not willing to let us have the information. Sometimes just the very information they want to give to us would identify them because they might be the only plant employee who would know that. That is unfortunate. It is true in any law enforcement situation, though.

MS. NESTOR: Okay.

MS. SEYMOUR: You hope that you can protect those identities and keep those things from happening, and you hope you have backup systems where people can come forward.

MS. NESTOR: I had some other comments on the prepared statement. This was one of my questions that I reserved from earlier today, the question of repetitive, and now under HACCP I guess it would be the question of a trend. One thing I am clear on is that there is no magic number, but that is about all I am clear on. Specifically I have a question about SSOP failures.

If a plant has repetitive product residue on product contact surfaces day after day except it is on different product contact surfaces throughout the plant, would that be considered a repetitive deficiency with the same root cause? In that case, say we are talking strictly that. How many criticals do you think would warrant calling the district office?

MR. SMITH: I will say it again. There is no magic number.

MS. NESTOR: Got that.

MR. SMITH: Okay. I will say again, and we have taught our inspection personnel, that they have a responsibility in documentation to document that they have direct product contamination, that there was a failure to implement and execute that SSOP and that they need to also identify there was a failure to enact previous corrective and preventive action that the plant has given us. I need them to make that linkage because isolated incidents are only isolated incidents.

Plants need to be put on notice, and this is when we make the determination. This is why I said earlier today if there is anybody in this room who is in plant management who receives a PDR that says there is direct product contamination or a critical on the deviation with a failure to execute that program, it is repetitive in that they gave

us previous corrective and preventive actions which either they chose to ignore, did not implement or did not execute. They are well on their way to one of the enforcement actions talked about in this paper.

I believe that paper lays this out. Again, when we look at these things we focus specifically on did you implement your previous corrective and preventive action. If I had somebody with product residue every day, I need to know why isn't their SSOP, which they have a requirement to do, working? What particularly did they say they were going to do to prevent it from reoccurring? If those things are not occurring that they said they would do, that's when I need to make that determination.

Now, there is no magic number because in some plants we have hundreds of people, thousands of pieces of equipment and hundreds of thousands of square feet. You cannot expect sterile hospital conditions every day and not expect on thousands of pieces of equipment to not find one piece of fat, let's say.

What I am asking our people to look at is did they carry out their program and is this an isolated incident or is this a continuing problem where we are not carrying out that program because your actions are totally different.

You still have a critical. Under the old system you still have a critical deficiency that you must address,

but it is an occurrence where you need to deal with that specifically, and it is not representative that the plant is not implementing their program or initiating corrective action. That's what I mean. All those things have to get wrapped in.

It's not an easy determination, and there can be no magic number. I will say it again. Any plant that receives a PDR under the old system or a non-compliance record under the new system which says you have direct product contamination or adulteration, failure to execute your program and, critically important, failure to execute previous corrective and preventive action to prevent it from reoccurring is heading down this path.

MS. NESTOR: By definition, in a pre-op sanitation violation there cannot be direct product contamination. Are you saying that this could not be triggered by pre-op violation?

MR. SMITH: I have been on record saying this a number of times. I'll say it again, whether folks disagree or don't disagree.

If we have applied the SSOP and the plant has released that area for production and we know that within 30 seconds or 15 minutes the product is going to be on that surface and is going to cause direct product contamination, we have instructed our people to write that up as a critical

SSOP failure.

I said that numerous times last year. We have taken action based on that. To my knowledge, we haven't been turned around on any of those on appeal.

MS. NESTOR: So under this system it would be unusual to find a plant that in three months failed 98 percent of its pre-op sanitation checks and got numerous criticals on each of those pre-op sanitation checks, on 98 percent of them? That would be unusual?

MR. SMITH: We would not expect to see that, no.

MS. NESTOR: You would not expect to see that? Okay. Thank you.

MR. HIBBERT: Bill Hibbert from McDermott, Will & Emery. This question is not from Tom Devine.

Dick, in your description of the process when you get to the stage when you are at the notice of suspension stage, as I understand it, I want to get clear, if I can, on if there is a disagreement. As I understand, if you are at the notice of suspension stage the language is that the Agency's belief is that the plant has failed to address the root cause of the system.

If the plant disagrees with that judgement, number one, what is the route of appeal? Number two, am I safe in assuming that that suspension of operations will not take place while that appeal is going forward?

MS. SEYMOUR: I will answer that. The route of appeal is always to the next highest level of supervision, and that would be provided in the notice of suspension. In this case, those are issued by district managers, so the route of appeal would be to Dr. Mina --

MR. HIBBERT: Okay.

MS. SEYMOUR: -- at that level and then continuing beyond that.

As you probably know through our repeating over and over again, when we are suspending inspection we have made a determination that we cannot determine that product is not adulterated. If we have made that decision, we cannot allow that product to continue to be shipped.

MR. HIBBERT: I guess what I am asking though is what happens when there is a disagreement over that very point?

For the sake of this discussion, let's assume the Agency is right a high percentage of the time. Let's assume it is right. It goes back to Bill's point. There is no magic number. There is a judgement call there. There is no magic number of PDRs. Someone is making an informed judgement as to the condition of that plant over which reasonable people could differ.

Let's assume the Agency is right 70 percent of the time, 80 percent of the time, 98 percent of the time. I

would assume that the Agency --

MS. SEYMOUR: One hundred percent.

MR. HIBBERT: That is the question. That is my question. It seems that this system, if I understand it, assumes infallibility on the Agency's part.

MS. SEYMOUR: No. Obviously as I said earlier, every decision can be appealed. If a plant presents information that we have made an error in judgement, and I think as we pointed out in some of the discussions this morning with regard to HACCP, we will bring a team of expertise in to look at those judgements when we do have a dispute.

MR. HIBBERT: But do you know prior to the imposition of the sanction?

MS. SEYMOUR: This is not an imposition of a sanction. The withholding of inspection is an enforcement action, not to impose a sanction.

MR. BILLY: In your hypothetical example, I assume there are a series of PDRs that have documented failures?

MR. HIBBERT: Yes.

MR. BILLY: Otherwise we could not be to the stage we are at, right?

MR. HIBBERT: Correct. Correct.

MR. BILLY: Were any of those PDRs appealed in your hypothetical example?

MR. HIBBERT: Let's assume that they were.

MR. BILLY: Okay. If they were and it was a situation where it brought into question what the appropriate action and follow up is then that would be taken into account in the decision process by the district manager and by Mark or anyone else.

If, however, at that stage there is just a set of PDRs and it is clear from the record that there has not been that kind of appeal, then you have a different circumstance. It would turn on all of the specifics of the situation.

MR. HIBBERT: I think that is my point. The question or the determination to be made about the status of a plant based upon a series of PDRs is different than the pursuit of an issue regarding an individual PDR. That is a separate Agency judgement. Are we agreed on that?

DR. MINA: No, I don't think we agree on that because I think what Tom is trying to explain to you, Bob, is that those notices of suspension do not occur in a vacuum.

There is a history that has been documented through the PDR process over an extensive period of time that articulated very clearly to the plant that the plant had not assumed the responsibility and corrected whatever the deficiencies were.

Now, there is a disagreement on individual PDRs

and the right to appeal those. We need to know what was the decision. Would those be sustained or overruled or changed because that changed the picture? Now, once we get to the notice of suspension, we have been through a process, a long process. We don't make those decision very lightly.

MR. HIBBERT: Right, but it is a separate decision. In other words, you are --

DR. MINA: Yes, it is a separate decision, but it is based on what happened the prior six months or a year or three months or one month or whatever happened before that.

MR. HIBBERT: But at that point the plant has no opportunity for appeal prior to inspection being held.

MS. SEYMOUR: You originally asked about suspension in the withholding actions. Those actions are for product to protect product from going out the door. It is a temporary action. It is not essential.

MR. HIBBERT: I am asking about suspensions.

MS. SEYMOUR: Okay. On suspensions we would expect that, as has been mentioned, at the time of PDRs or in the future non-compliance reports, at that point the appeals would occur if there is a disagreement of fact or a disagreement of interpretation, of requirements or significance of a problem.

We would expect, as Bill pointed out, that as a plant starts to get to the point of a repetitive problem

that the PDRs or non-compliance reports would indicate that and would say here is what was wrong. Here is what you said you were going to do. Here is what I found when I went back to check.

Up to this point in the instances where we have taken suspension actions, we have found the history in that clear trail of sequence of events. I was being not completely facetious when I said 100 percent. We expect to be 100 percent right before we take these actions. That doesn't mean we're infallible, but we are doing everything we can to be 100 percent right.

We don't accept anything but doing it exactly right in providing the plant appropriate notice, providing appropriate documentation and providing the appeal rights and listening. Our objective isn't to shut down. Our objective is to get correction.

MR. HIBBERT: But should you fail even in one case in the goal of reaching 100 percent, that plant will not operate based upon your independent judgement that there is a systems failure.

MS. SEYMOUR: I would say that that is a risk that one would have to take to protect the public from adulterated product in all the other instances.

MR. HIBBERT: Thank you.

MR. BILLY: Caroline?

MS. SMITH-DEWAAL: I will hold my question and submit it to the Agency in writing.

MR. BILLY: Dennis?

MR. JOHNSON: Dennis Johnson, Olsson, Frank & Weeda.

I have a little bit of a follow up to Bob's question in some regards. I want to get the process down, and I do not know if he has skimmed over something or not.

I guess as an initial matter, you would not suspend for PDRs that are on appeal. In other words, you would allow a plant to take an appeal of a PDR. If a decision has not yet been reached, you are not going to use that as the basis of an action.

Second, you have been mentioning notice. Is the notice over and above the PDRs? In other words, are we going to go ahead and say hey, guys, it ain't working, and we want you do to more? Is there going to be any of that feedback from the Agency?

I would kind of like to know if we are going to get a little glimmer of the bullet before it gets shot and also whether or not we have a chance to prevent the loading through the appeal process. I would like to start with that before I get to even Bob's concerns.

MS. SEYMOUR: We would not stop the action that would be underway just because of the appeal. We cannot

have that. Otherwise everybody would appeal everything to keep everything --

MR. JOHNSON: I am sorry. We are assuming there are things in front. In other words, you are not going to close someone down for their very first PDR.

MS. SEYMOUR: That's correct.

MR. JOHNSON: I know there is no magic number. Let's assume --

MS. SEYMOUR: We could have on the first PDR -- I want to clarify that -- if the situation shows the processes are totally out of control in the plants.

MR. JOHNSON: Let's not assume that scenario. Let me use condensation, which is probably everybody's favorite. See, I told you it was everybody's favorite.

You have a condensation PDR on Monday. You have a condensation PDR on Tuesday. The plant appeals both of them saying there was no direct product contamination. We disagree on the facts. We disagree on this. On Wednesday there is another PDR that comes down, and that one the plant automatically takes up. On Thursday, the inspector says I am going to withhold.

You have PDRs Monday, Tuesday, Wednesday and Thursday. Even though Monday's is on appeal, Tuesday's is on appeal, Wednesday's is on appeal, are you going to use those as the basis of withholding the mark because we then

have not gotten any due process or appeal rights?

I am not saying this might ever happen. I would just like to know that we do have the opportunity to challenge from the word go. If we forego that opportunity that is one thing, but I would like to know if indeed you would take action on the basis of PDRs, all of which are on appeal.

MS. SEYMOUR: I'll give it a shot. I think there are just too many hypotheticals in your question there to answer it directly, but we would never say that we would not take action just because there is an appeal underway. If we need to take action to protect product, we are going to take that action.

Now, the compliance officer does go to the plant and conduct interviews, prepare documentation. We look at things beyond the PDRs. The plant is given an opportunity to give a statement and to present information at that point. Plants present information to district managers.

The thing again to remember is on condensation, your example repeated three days in a row. If there is a condensation problem three days in a row, there is a preventive measure that is not working in that plant, so the plant should be focused on that and not on appealing whether product was present or not because product is going to be present.

MR. JOHNSON: Well, we can vary the facts.

MS. SEYMOUR: Yes, but we want people to focus on the corrective and preventive measures.

MR. JOHNSON: But if we are working on the preventive measure we disagree that there was direct product contamination so we have a factual dispute. We have the plant actually trying to do something, but cannot handle necessarily condensation, the total cure within two or three days.

I was just curious as to whether or not we have a bite at the apple sometime before the trigger is pulled. I guess what I am hearing is it depends.

MS. SEYMOUR: We will always look at appeals and take them into consideration. If we are wrong, we will do something about it.

MR. JOHNSON: But I was wondering whether you would withhold the use of the mark?

MS. SEYMOUR: If we think we are not wrong.

MR. BILLY: Do you mean what would our hypothetical action be in response to your hypothetical situation?

MR. JOHNSON: It works for me.

MR. BILLY: We hypothetically would take action.

MR. DURFLER: One of the things that you have to keep in mind is that this statute puts the burden on the

Agency to find that the product is non-adulterated. We have to make that judgement.

I understand the context in which you are asking the question and everything like that. I am going to put a different spin on the rule making. When it starts we are going to be really interested in your comments, and we raise a lot of these issues in at least the preamble.

I think ultimately the Agency has to make a determination as to whether or not the product is adulterated. That is a significant aspect of this that you cannot lose sight of.

MR. JOHNSON: Right, but what I am saying is you are assuming you can make that decision on the basis of a factual dispute involving one aspect. In other words, you are in effect closing a plant down. You are putting an injunction in place that we can never work around. It is an automatic per se. We cannot trust you even though we have not given you your due process right, and we are going to close you down.

MS. SEYMOUR: Since you are kind of semi quoting what I said or paraphrasing what I said, that is not what I said.

What I said is we would consider legitimate appeals at any point in the process. We have said in our remarks please do not wait until we have taken a withholding

action to appeal something you disagree with because then we do get into these locked in positions.

MR. JOHNSON: That is why I started my hypothetical with we appeal right away.

MS. SEYMOUR: Okay. Appealed right away? If there is a basis for the appeal and there is a factual dispute, we need to get that resolved right then because we are dealing with whether product is contaminated or not.

MR. JOHNSON: So we will deal with it right then before we suspend? It depends?

MR. VANBLARGEN: I think in both of those hypotheticals, the one that Dennis gave and the one that Bob gave, there is one important element. We would not be taking the withholding action unless there were existing conditions in the plant at that time in which we felt we had adulterated product.

MR. JOHNSON: So if I fix the condensation or it was not affecting product, in other words you would do it for present tense and not just past tense?

MR. VANBLARGEN: Yes. You are going to be looking at the record as it is developed, and we are going to be looking at the corrective and preventive actions as to whether or not they have been instituted and effective in the way they have done.

If we have deficiencies in that plant existing on

that particular day that show that those preventative actions were not either implemented or not effective in precluding direct product contamination, we are going to withhold on that basis, and we are going to take product control action at that point in time, too.

MR. JOHNSON: But if it has been corrected and you do not have any product contamination that day, you are not then going to use those ones on appeal to say your system was out of control? In other words, you are going to have to tie it into that day?

MR. SMITH: Again, Dennis, I just want to drive home this point one more time. If you are getting PDRs that say there is direct product contamination, there is failure to implement your program and failure to execute corrective and preventive action and you do not agree with that, you need to appeal immediately the first time -- immediately -- because when you are getting that word, that kind of documentation, you know you are going down that path.

You need an immediate appeal, and you need a very rapid response. We will commit that we will rapidly respond. We have put 24 hour/seven day a week procedures in place to do that both at the national and at the district level.

I hate to talk about hypotheticals, but I will say direct product contamination, failure to execute, failure to

execute the plan, failure to execute corrective action. If you don't agree with any of that or your client doesn't agree with any of that, you need to be appealing that immediately because we will act on those things if they are not appealed.

MR. JOHNSON: You said you would act on those things if not appealed. What I am asking is real simple. If we disagree and appeal immediately, are we going to have the withholding action imposed simply because these allegations occurred in the past?

MS. SEYMOUR: If there is a repetitive occurrence of the same deficiency, there will be a withholding action even if the previous PDR or non-compliance report is on appeal.

We want to resolve those appeals very quickly, though, so we wouldn't expect it would be on appeal for a long time. I mean, it should only be on appeal for a few hours I would think. If there is really a dispute of fact, we need to get somebody there to look at the facts and resolve the matter.

MR. JOHNSON: I did not mean --

MS. SEYMOUR: I'm sorry. Regarding the question this morning about compliance officers and availability, I might take this occasion to answer that.

We would expect to have a compliance officer on

site within 24 hours in any location in the country. We are trying to be prepared for that when there is an action to withhold. We expect that that time will be much less than 24 hours in most cases. It should be only a few hours.

We also expect that circuit supervisors and other appeal levels that the people can come and if you are saying there is no condensation or it is not in a product contact area, we need to get somebody in there to confirm the facts.

MR. JOHNSON: I do not mean to monopolize. I really only have one other question. I will put it away.

If you go for a complaint down the road, if nothing else happens and you are asking for withdrawal of inspection, what exactly is the remedy you are asking for from the ALJ precisely?

MS. SEYMOUR: The Administrator files a complaint with the Administrative Law Judge to withdraw the grant of inspection.

MR. JOHNSON: To withdraw the grant of inspection. Okay.

MS. SEYMOUR: If the Administrative Law Judge agrees with the Administrator, that is what occurs.

MR. JOHNSON: Thank you very much. I did not mean to monopolize.

MR. BILLY: Kim?

MS. RICE: Kim Rice, American Meat Institute.

Dick, you can clarify something on Page 3 in the top paragraph. The new organization enables FSIS to use the training and expertise of compliance officers to assist in plant inspectors in documenting failures of plant control systems and helps to assure appropriate due process when enforcement actions are needed.

Can you just clarify exactly what that means?

MS. SEYMOUR: Dick did not write this. I wrote this.

MS. RICE: Okay. Can you clarify?

MS. SEYMOUR: He can try. He might actually explain it better.

MS. RICE: Can somebody clarify?

MS. SEYMOUR: Are you asking about the due process part? Is that the part?

MS. RICE: No. The training and expertise of compliance officers to assist in plant inspectors.

MS. SEYMOUR: The compliance officers are available not only when we do have a withholding, but in the proactive mode also mentioned to go in and work with inspectors in terms of the documentation that they are putting together.

We also are encouraging districts when they do get to that point to let the plant know that this proactive work is underway and that the documentation is developing and

that the plant needs to get on top of the situation.

Is that clarifying for you?

MS. RICE: I think so.

MR. BILLY: Felicia?

MS. NESTOR: Felicia Nestor, Government Accountability Project.

I have some concern about the last paragraph. It says that the enforcement actions represented an enormous drain on Agency resources. Also in that paragraph it talks about fairness to plants and consumers.

Listening to what has been said here today, I think that if someone who did not know anything about plant records read the transcript of this meeting, they might think that it is unusual for a plant to have three consecutive days of condensation or a certain number of repetitive PDRs.

I am very concerned about the Agency's responsibility to consumers. If you expect yourself to be 100 percent correct before you do anything, especially when you are giving the plant the out of a suspension in abeyance, I do not know that you are protecting consumers adequately.

The 70 criticals on the 98 percent failure on SSOPs was not a hypothetical. This is the Hudson Source Plants, and they failed every one except for one or two in a

three month period of time with numerous criticals in pre-op. They also had at least four days where product was falling on the floor in the packaging and boxing area and employees were standing there continuing to work. Nothing has happened in this plant. That is just part of what went on in this plant.

I know of two plants in one state each of which had other 2,000 PDRs at this point. It sort of boggles my mind that there cannot be at least one repetitive deficiency in there with 2,000. I do not know how much failure you can get.

I also know of another plant where there are 800 PDRs. The documentation was described by the compliance officer as exemplary. There is beautiful linkage and everything else. This plant was not put under an enforcement action.

I looked at an enforcement action that did take place. It was a little mom and pop plant. They had six failures on their pre-op sanitation. I do not understand how it is possible for one plant to be put under a compliance action for six failures. I compared them. They are very similar. We are not talking about large product residue at the small plant and little specs at the big plant.

I don't exactly know what question to ask, but in

looking at my FOIA documents and the problem that the industry is asking, I do not see that that is the problem. It seems to me that it is the opposite problem.

DR. MINA: Felicia, I would like you to share the specifics in those cases with me so we can follow up on them.

MS. NESTOR: I will do that, Dr. Mina. The only thing that concerns me about that is that I know that you all have been informed in many of these cases. I will be happy to do that. I will be happy to do that.

DR. MINA: We want to protect the consumer. If those situations do in fact exist, I want to follow up on it.

MS. NESTOR: Let me ask you this. The Hudson Source Plants. Compliance went into each of the Hudson Source Plants, correct, and did a review of the records in each of those plants?

If there were repetitive failures, even if the inspector and the IIC and the circuit supervisor and the district managers in those cases failed to take action, the compliance officers that went in and did the review of the Hudson Source Plants would have had the opportunity to see the documentation.

From my standpoint, Hudson, Beef America, 18,000,000 pounds rejected by Korea. That all says

something is going wrong here.

MS. SEYMOUR: I am not sure. Was there a question?

MS. NESTOR: Yes. The question is if down the road Hudson Source Plants continue to be responsible for massive recalls or massive outbreaks that are traced back to them, can the consumer blame the compliance officers that went in and did those reviews?

Were those reviews adequate enough for FSIS to have notice that those plants are really out of compliance, or is the consumer still having to decide well, no, it might have been the IIC or it was the circuit supervisor or it was the district manager that made the wrong decision?

MS. SEYMOUR: I will try to address that.

MS. NESTOR: Did compliance have the opportunity to make a review?

MS. SEYMOUR: Compliance did review the Hudson suppliers on a certain window of time in the Hudson production. We did not review all Hudson suppliers because we were able to isolate a period of time that seemed to be the most likely time where we knew there was a problem.

MS. NESTOR: And what was that period?

MS. SEYMOUR: I am not sure I can give you that. I do not know it, number one, and that is a matter under investigation as well.

We did look at all of those plants. Our hope was that we might be able to isolate one or more particular problems that would have perhaps led to this so we could learn from that not in an investigatory mode in that regard.

We also were in an investigatory mode in those plants or we shifted into that at points where we determined that there might be an enforcement problem, so we did both. We were looking both at the overall systems to see if we could learn and looking at the compliance of those plants.

MS. NESTOR: So you were not just reviewing Hudson? You would have considered a compliance action if you looked at the records and felt like it was warranted?

MS. SEYMOUR: If there was a basis in the files. Now, in the instances where we did go in, we did follow up on some specific findings in the plant, but none rose to the level of a withholding or a suspension.

MS. NESTOR: Thank you.

MR. BILLY: Someone down there had their hand up.

MS. MARCOUILLER: I am Sherry Marcouiller with Kraft Foods, and I have a question about the non-compliance record form.

I would like to switch the hypothetical to a group of plants that we could assume are basically well run plants, but in the course of putting out 2,000,000,000 packages a year or so are going to have issues that are

going to produce non-compliance records from time to time.

There are a couple slots here for plant management's response, both immediate and with further planned actions. I have also heard a fair amount of conversation about the topic of appealing where there is some disagreement.

We did discuss this a bit when the SSOP requirements were introduced. At the time, one of the things that we had suggested is that it may be a better use of everybody's resources in certain cases for the plant to simply document some more facts from their side of the story, if you will, into the record and not necessarily formally appeal virtually everything that is coming up where we may think that someone looking at a record six months or a year from now would find certain information that is not written up by the inspector to be relevant.

In other words, is there an opportunity not to make a big issue out of everything, but still protect the company's record? The specific question is what instructions, if any, are being given to the inspectors in the plant about how they should review the company's responses that come back on this form because in some cases where we have tried to add context, we have been told that that requires rejection of our response.

MR. SMITH: Well, I will talk to what we are

teaching or training our people.

Both with the SSOP and with the HACCP, we have always reiterated what is known for a fact and reasonable to conclude. If you have more facts that would change the determination, we have not instructed our people to reject those in any way.

Again, I think we have moved fundamentally to a systems approach. Critical to that systems approach is we are verifying that the plant is doing what it said it would be doing.

If we are documenting that it is not doing what it said it was doing either through SSOPs or HACCP, then I think that is a serious finding because you developed the plan or the plant developed the plan. The plant said these are the things that are going to be carried out. If we're documenting they are not doing those things, then I think that is serious concern.

We have removed the classification. I remember at this time last year there was a great debate about the classification issue. We have totally eliminated that classification issue I hope, and we have in the non-compliance record focused on food safety versus everything else, have separated that out, have developed different regulatory models for that specific purpose to draw everybody's attention to food safety.

I will reiterate again that if we are not in agreement with an inspector's characterization of a food safety failure that we need to appeal that and get that right away because we do have them focused on making these determinations. That is the model I put up there, system failure. Continuous food safety failure would lead them to conclude that there is a system inadequacy in that situation. It is very important.

Your records. Again, if you are finding things and documenting you found them, then HACCP is working. The system is working. The same thing with SSOPs. That is what we are looking for. We don't expect 100 percent perfection.

I think there are differences. We hear of hundreds and hundreds of PDRs or deficiencies in some plants. Yes, I have seen a number of deficiencies. Things like fat on the floor and paper in the corner and the inspector's office was not clean are sanitation deficiencies. They are not critical direct product contamination deficiencies.

I would hope that this Agency and our people are making decisions based on direct product contamination and preventing adulteration or product being shipped that is adulterated into commerce. That is what we have trained our people to focus on.

To the extent I know that we are accomplishing,

that has been our focus, and our evaluations and audits have said that that seems to be where our focus is placed.

MR. BILLY: Caroline?

MS. SMITH-DEWAAL: Tom, have we transitioned from the questions portion on enforcement to the discussion portion more generally?

MR. BILLY: What do you think?

MS. SMITH-DEWAAL: It seems like we were getting into a lot of discussion.

MR. BILLY: Okay. Go ahead, Caroline.

MS. SMITH-DEWAAL: I have a point related more to --

VOICE 3: Tom, we have an enforcement question before you go on with the discussion.

MS. SMITH-DEWAAL: All right.

MR. BILLY: Okay. Enforcement?

MS. STEWART: Dee Stewart. I believe you just answered it for me.

I was just wondering in monitoring of the records if they find that we have failed a CCP and that we have corrected it ourselves, then a non-compliance would not be written up on that matter then?

MS. SEYMOUR: That is compliance.

MS. STEWART: Okay.

MS. SEYMOUR: That is not non-compliance.

MS. STEWART: He was just answering that. What I am saying is if you are reviewing the records and you see that we failed a CCP, but we did correct the situation.

MR. SMITH: Again, absolutely, but I always like to underscore and take an opportunity to say that that means all provisions of either 417.3(a) or 417.3(b) have been met of accepting that corrective action.

MS. STEWART: Okay. I have one more question for enforcement.

When you are verifying the records in shipping before a shipment, say if you have your lots broken down to an hour, every hour is a lot, does the entire lot have to be produced before it can be shipped, or is it just whatever is going on that truck?

MR. SMITH: Again, I think that is your operation, and I think we have already said earlier that we would put a paper out on this.

I can say we do recognize that monitoring can be done continuously, verification can be done continuously, and plant record review can be done continuously.

MS. STEWART: So it does not really have to be per lot?

MR. SMITH: Again, the wording in the regulation I believe is on specific production. I am not sure. I think what works for you, as long as you can determine that the

critical limits have been met and meet the requirements under the prior to shipping in the regulation. You have to know whether you can meet that with your situation.

MS. STEWART: Thank you.

MR. BILLY: Jim?

MR. HODGES: Question for Carol or Dick. When compliance is called in to determine the legal sufficiency of the records in preparation for some type of withholding action, does the compliance officer conduct a physical review of the plant?

If he conducts a physical review of the plant, to what degree is that factored in in your decision to take additional compliance action versus simply looking at the past history of the records that may document that you should take that action?

What I am driving at is if there is a plant review and the plant review says that there is no deficiencies in that plant yet the records do document that there has been a history there, how do you factor those two together?

MS. SEYMOUR: I will answer it in two parts. Number one, each case is handled individually. There may be instances where we definitely want the compliance officer to conduct a physical review of the plant. We may want to make pictures. We may want to do other forms of documentation.

There are so many varieties of cases. There are

huge plants that we certainly would not expect the compliance officer to do a total review of the plant before we made a decision. It would vary from case to case.

The second part of your question is would we factor in if the compliance officer found information that was different than what the inspector had reported. Of course we would consider that, if I understand your question correctly.

MR. HODGES: My question centers more on if the plant has corrected the deficiencies that may have been noted in the past, and, if you will, during your physical review there is a clean bill of health of the facility. How does that factor into your further determination that a withholding action should be taken?

MS. SEYMOUR: I think there are two things on that. Number one, if that has occurred, that is a step in the right direction obviously. The clean up is a remedial action, and we are looking for preventive actions.

We would expect that when we reached a situation where we had repetitive deficiencies due to the same root cause, we expect the plant to clean up. I mean, that is just sort of a given. Some may not. If they are down, they may not bother to clean up. We do expect an immediate clean up will occur, but we are looking for more than that.

If you will turn to the items in the speech, we

sort of gave you an overview of what those items are on Page 5 that we would be looking for. That is not an exact template, but that shows the kinds of things we would expect.

MR. BILLY: Bernie?

MR. SHIRE: Thanks, Tom. Bernie Shire, American Association of Meat Processors.

I have been sitting here most of the day listening to the discussion about HACCP and now more recently compliance. My question really has to do with the compliance end of things. It is kind of a question and a statement, I guess.

I guess my question was basically I understand that under the system now that compliance has been pulled into the district operations and that they work physically in the same location and that previously there was more of a separation. The question I have is as to why that is being done.

My observation is that it seems that with all the discussion about HACCP, and nobody really knows what is going to happen until it actually starts, but it seems from just looking at it that I do not see that any real standards have been developed or really articulated about why and how long it is going to take for plants to have their mark of inspection withdrawn.

I just wonder if this is a decision that is going to be made on the spur of the moment? Who is going to be making this decision? Has there ever been any kind of consideration given to in the appeals process an outside third party? How can people really appeal the compliance decision once that is made? I do not see a real good system setup there right now. I do not see a real means of review for compliance.

It seems as if the whole system is moving toward a way of making it easier for the Agency to pull inspection from plants, to pull them and make the plants stop operation not necessarily without a real scheme, if that is the right way to put it. Maybe that is something we will not know until things actually start, but at this point it seems as if there is not a real means there set up to do this. That is my comment.

As I say, my question has to do about the compliance and inspection being a lot closer together and what the advantage of that is supposed to be.

DR. MINA: I will try to address the first part of your question. The reason we combined compliance and inspection as part of our reorganization is in putting all the delivery in it, if you will, the field delivery unit under one umbrella. That is the field operation umbrella.

We also viewed that the inspection work and the

compliance work is very similar. All distinctions are not valid today. An inspector in a plant enforces the requirements to achieve compliance. The compliance officer does the same thing. Traditionally they had done it outside the plant.

Also in terms of supporting the inspector in terms of having the proper documentation, the compliance officer had been trained to do that. We have not trained our inspector as well as we train our compliance office to do the proper documentation to support the case file. They have been extremely helpful in working with the inspector in the plant to determine the adequacy of the documentation.

That is one of the principles of the reorganization is to have all the field delivery units under one umbrella.

MR. SHIRE: It seems maybe then you end up with the judge and the jury and the policeman all in one spot. I am not sure that is necessarily a good thing either as far as the plant is concerned.

DR. MINA: That is your characterization of it. I think we view it a bit differently.

MR. SMITH: I just want to add to your comment. I think we would say that we have standardized our decision making process on enforcement protocols under 417.6 of what determines an inadequate HACCP system in the regs. I think

we have been very clear on that in the situations we have talked about.

MR. SHIRE: I guess what I mean is when it comes into the real world though and decisions are made on individual plants. I wonder whether the standards are there and whether everybody is going to be treated equally in each regard in that way? That is what I am wondering about.

DR. MINA: We are committed to due process. We also support the appeal process. We will respond to those appeals in a timely manner.

As you know, there is a directive out that goes into great detail about the steps that we will go through to respond to appeals. I think it is an improvement over the system that we had in place in the past.

MR. BILLY: I would like to add one other point and that is to remind you again of the two paragraphs on Page 6 of the paper on the application of concepts during the past few months, Bernie.

It would seem to me that at least in terms of SSOPs, some of the concerns that you raised did not manifest themselves. Perhaps we can take some comfort in that experience. We have laid out I think pretty clearly a parallel and similar approach that we are taking here under HACCP.

MR. SHIRE: That is true, except HACCP is much

more of a massive undertaking --

MR. BILLY: I understand.

MR. SHIRE: -- especially for small plants.

MR. BILLY: You will have the benefit of this first round to learn from.

The fellow down at the end?

MR. DANDREA: My name is Mike Dandrea. I am with Shadybrook Farms. My question is for Carol.

When the trend analysis starts and let's say January 26 rolls around, are we going to be forgiven for all PDRs prior to that date and then start with a clean slate as far as trend analysis?

MS. SEYMOUR: I am a little tired. I will say there is no magic number.

Obviously there is a major change that occurs when plants implement HACCP. We are more interested in what happens in the future than what happened in the past, but if we have a history of non-compliance that was occurring before HACCP and we start to develop a history of non-compliance under HACCP, we are going to act much more quickly in that case than somebody who is first starting out. That is where our priorities would go.

I would say that anything that can be done to get ready for HACCP, the things that you need to do include making sure that anything that might be pending now is

resolved and taken care of now before you shift over.

MR. BILLY: All right. Let's open it up now for other points and concerns people have. Just consider this sort of London, and this is Hyde Park. This is Speaker's Corner right here.

Caroline?

MS. SMITH-DEWAAL: Caroline Smith, Director of Food Safety for CSPI. I have two questions. The first is a specific question, and the second is a more theoretical or general question.

The first is with respect to your announcement today that there will no longer be mandatory trimming in plants that come under HACCP to enforce the zero tolerance for fecal contamination.

Will there be any change in how the inspectors treat carcasses where there is visible fecal contamination? Today, based at my observations at a meat plant, they rail those carcasses. Will there be any different treatment by the inspectors?

MR. SMITH: On line, no, because it is still part of the postmortem inspection procedure. They would still rail them out if that is the case or stop the line if that is the case, depending.

Each carcass will have to pass. It will not have fecal material on it at the front of the rail. We use our

on line inspectors to do that at this point.

MS. STOLFA: The Federal Register notice that we talked about this morning that was published on November 28 set out our policy and set out our thinking that the zero tolerance standard for fecal contamination in both livestock and poultry was a food safety standard and gave the signal that we intended to continue to perform inspection verification checks at the same point and at the same frequency as we presently do.

There was also an issue paper on the registration table that set forth what might be the next steps following the settled implementation of HACCP in large establishments.

MS. SMITH-DEWAAL: On to my more theoretical question. This is a challenge that I think both --

MR. BILLY: Is this different than a hypothetical question?

MS. SMITH-DEWAAL: It is. It is. This is not a hypothetical. This is a theoretical one. The challenge is not only to the Agency, but I think also to the industry.

I am raising again this very issue of whether evisceration should be considered a critical control point. I would like to put on the table the concept that today in fact evisceration is treated as a critical control point, but we have federal inspectors that monitor that critical control point.

An example of that is the inspection for zero tolerance where they check for visible fecal contamination on carcasses. Also in the poultry plants they check the birds and remove them from the line. The checks are frequently done right around evisceration.

I would like to put on the table the concept that in fact today evisceration is a critical control point. It may not be one that is monitored today by the plants, and that may be a legitimate reason why in a HACCP plan that critical control point you would have monitoring done by the federal inspectors because in fact that is what is happening today. I am concerned at the concept that we are going to somehow implement HACCP and miss that point as a critical control point.

MR. BILLY: Ken?

MR. BYRD: Ken Byrd with Pilgrim Pride. I have a couple of questions just to be sure that I am on the right track.

I understood that the pre-shipment review could be done on a continuous basis before the lot was completed so long as all CCPs and corrective actions on that product are within compliance. Is that correct?

MR. SMITH: Yes.

MR. BYRD: All right. FSIS Directive 7640.1 dated September 24 has to do with the inspection duties on quality

control programs. The prior approval of quality control programs and in plant procedures was done away with with the exception of five quality control programs.

Regarding the issue of in plant reprocessing and the monitoring of reprocessing, the directive says that the monitoring of these CQ procedures will be done as a PBIS task. Does reprocessing fit into one of those in plant procedures? What is the inspection role in monitoring the reprocessed product? Is it as it has been in the past, or is it done as a PBIS task? Where is that?

MR. SMITH: Again, as Pat said earlier, any food safety hazard we would expect to be addressed in the HACCP plan. Reprocessing food safety hazards we would expect to see there in the HACCP plan. Anything else, yes, we will pick up then in the product wholesomeness section of the inspection system procedures.

Those requirements can be found as part of Attachment 8 of the 5400.5. We would direct you to Sections 04 and 06. Here is one that says Facilities and Equipment, Inspection Reprocessing Station. The facility requirements associated with that would be found under that procedure, 06(d)(02). That is on Page 6-5.

We want to reiterate again the food safety hazards associated with reprocessing or any CQ program we would expect would be addressed through the HACCP plan.

MR. BYRD: But the question was inspection monitoring of it.

MR. SMITH: Again, that is dependent on if it is part of food safety. We described earlier that we would be verifying that through our 01 or 02 procedure. If it is not, we would be verifying it by performing these other ISP procedures.

MR. BYRD: Another question. With the whole concept of pathogen reduction and issues of that nature, newly merging technologies for pathogen reduction such as maybe ozone, where would that be today, specifically ozone?

MS. STOLFA: I think that we presently have a new technologies group that after appropriate FDA approvals of various technologies have been concerned. Our new technologies group has the purpose of working with companies and assisting in demonstrating the effectiveness or the practical usefulness of those technologies in USDA inspected plants.

My understanding is we have some work going on. Now, I am not as close to that as I used to be, but my understanding is we have some work going on with ozone as a new technology.

I think further we would expect that in the future there would be a lessening of Agency procedural requirements in terms of companies being able to move directly into using

new technologies once they had secured basic FDA approval.

MR. BYRD: So there is more of a fast track today than what there has been in the past?

MR. BILLY: Plus as a general policy we really encourage new technology.

MR. BYRD: Okay.

MR. BILLY: We think it is fundamentally important as part of this transition to HACCP and pathogen reduction. It is good to look at new technology and try to apply it in these plans to address these problems.

MR. BYRD: One other issue, and then I will hush. I always say I am going to come to these meetings and keep my mouth shut and my ears open, but somehow I don't always do that.

In the overall concept of the HACCP system where the plant monitors the process, if something has gone wrong the plant finds it, they fix it, they take control. They take any corrective action that might need to be done. They bring everything back into compliance, the idea being that that is what they are supposed to be doing, and an NR not be issued. If someone does a monitoring test and something happens, they do not get this recorded on the chart.

Later a verifier comes by or the pre-shipment review, either one of those. They find that this has not been done. They take corrective action. They take

preventative action and the whole nine yards. They fix the problem, but yet the plant does get an NR for that.

That seems a little -- what is the word I am trying to say -- contradictory to the concept of finding the problem and fixing it.

MR. SMITH: Again as you described it, and we are talking hypotheticals. As you described that and knowing all things, I could see in that particular situation we may not issue a non-compliance.

What is critical to that determination, and we have not taught this to our folks, but we have discussed it in facilitative training. We have just not trained it. You would respond with a corrective or immediate and further planned action. Walking by, catching it and putting initials on it does not fix it.

MR. BYRD: Right.

MR. SMITH: Walking by, catching it, putting something in place and verifying that it is working. If that is the type of corrective action, I would agree with you. We do not want to document that as a non-conformance. That would be the conditions under which we would not do it.

MR. BILLY: There is language in the preamble to the final rule that talks about applying common sense. We want to do that. Failure to note something can happen. We can do it. The plant can do it. It has been spoken to

earlier. We are trying to take a common sense approach.

If an inspector sees a situation, though, where on the same critical control point it is happening twice, it is happening again, you know, you can get into a different circumstance. It will turn on the circumstances. That is how we are trying to approach this.

MS. STOLFA: I also want to make sure that you do not start to act as if monitoring were not a serious part of the HACCP plan or not a serious regulatory requirement. Monitoring and procedures of monitoring are serious, important parts of HACCP plans. They are not throwaways.

It is fortunate that following monitoring there are lots of other procedures through which one can deal with a deviation of a CCP, but I do not think we want to give the impression that this is not something that people should try to do as well as their HACCP plan suggests they ended to do it.

MR. BILLY: Bernie?

MR. SHIRE: Thanks, Tom. I just want to ask a question.

We have a few companies that will be coming on line, but most of our people will be coming a little further down the road. In a way I guess the large companies will be kind of guinea pigs for some of our folks.

Quite awhile ago we had made a proposal to USDA

about the possibility of having some small plant pilot demonstration projects. There was a lot of discussion about this, and the Agency did set up a program which was very helpful which turned out to be more in the realm of instruction to people in terms of doing HACCP, although the Agency did point out that it was really technical assistance and didn't qualify as training per se under the regulations; at least that is what we were told.

The idea we had in the beginning was to maybe work with the Agency with a couple of plants, and we had a lot of plants that volunteered, to maybe actually set up a few pilot projects just to see how HACCP would work in settings this size. Since there is a bit of time yet and we are about a year or a little more away from when the smaller plants come on line, we wanted to make this request again and see if this is something we could work on since we have that amount of time.

I am bringing that up here that over the next year or maybe even the next couple of months that we could set up a program that could last a couple of months in just maybe a few plants just to see how the process works and if there are any particular problems. That would help everybody in terms of when we and other industry associations do training and when you do training as well. I would just like to make that request.

MR. BILLY: Yes, ma'am?

MS. PHILLIPS: Hello. I am Patricia Phillips, Phillips Resources.

In looking at Page 56 of the 5000.1 form, my question concerns the nine different processing categories. As Rosemary pointed out, this basic compliance checklist is put in the negative in almost every instance except for the first item on the reverse side of the page, which talks about multiple products.

It says if the HACCP plan covers more than one product and the products are not within one of the nine processing categories, which would seem to be a fairly common item where you might have ground products and unground products produced in the same plant.

Am I correct that this question is not in that negative parlance --

MS. STOLFA: No, you are not correct.

MS. PHILLIPS: -- that the rest of the questions are in?

MS. STOLFA: The question is in the negative. One cannot have a HACCP plan that includes products from two different of those nine processing categories. One can have a HACCP plan that includes multiple products as long as they are within one of the nine processing categories.

MS. PHILLIPS: So then a plant might have multiple

HACCP plans?

MS. STOLFA: Yes, multiple HACCP plans. They might have as many as nine if they chose to go that way and if they had that many different types of products.

MS. PHILLIPS: Well, they would have to go that way, would they not, if they had products in two different categories? They would have to have two different plans.

MS. STOLFA: They would have to have at least two different plans.

MS. PHILLIPS: My other question would be they might have metal detection as a critical control point in one plan, but not in another based on the type of product or the process?

MS. STOLFA: Certainly.

MS. PHILLIPS: Thank you.

MR. BILLY: Yes, sir?

MR. BYRD: Ken Byrd, Pilgrim Pride. Another dumb question.

In view of the last commenter's question and the response that you can only have products of one category in a HACCP plan, you cannot have products of two different categories in the same plan. In the further processing -- let me back up.

In the processing area of let's say a poultry plant through slaughter, through the chillers, then through

packaging and boxing, etc., after the chill system is this still considered to be slaughter, or is this considered to be raw-not ground? If so, this would be in two different categories. If that would be the case, the generic model shows it all in one plan.

MS. STOLFA: They are a sequence, right?

MR. BYRD: It's a sequence, yes.

MS. STOLFA: You slaughter it, and also you maybe cut up or package and sell as raw product?

MR. BYRD: You slaughter it, you package it, you sell it as raw.

MS. STOLFA: Is that not raw-other?

MR. BYRD: Raw-other?

MS. STOLFA: Yes. You do slaughter first because slaughter is a process.

MR. BYRD: My question is in the generic model it shows it all under one HACCP plan.

MS. STOLFA: I think that is okay in that slaughter is like the first step. What we are saying is you cannot cross categories. You could not have raw-other and then a processed product both in the same HACCP plan.

MR. BYRD: Raw-other and processed?

MS. STOLFA: Yes. If you used raw-other as a model and you used that, you put slaughter first, you did raw-other and together you built a plan that covered your

packaged cut up product going out the door.

MR. BYRD: I guess my point there was I was considering that to be a raw-other, which would be a different category than slaughter.

MS. STOLFA: No. I think slaughter is like the first step of what ends up being in many instances raw-other going out the door.

MR. BYRD: So raw-other would not be a different category than slaughter, but it is listed as a different category in the nine.

MS. STOLFA: In some instances people do not sell directly to consumers in one of the other process categories. We have to cover slaughter.

MR. BYRD: So in that case then it would not be in a different category? If you slaughter it and you box it and you sell it, then that is all one process under slaughter, but if you do anything else to it, if you cut it up or anything like that, then that is a raw-other? Is that correct?

MS. STOLFA: Yes.

MR. BYRD: As long as you just kill it, chill it, put it in a box, label it and sell it, then that would just be all slaughter? Okay. Thank you.

MR. BILLY: John?

MR. COOL: Yes. John Cool from Thornapple Valley.

I would like for you to just draw a comparison for me in considering CCPs, a comparison between reasonably likely to occur and what we may have used in determining whether it would be a CCP as low risk.

MR. BILLY: Yours is low risk?

MR. COOL: If we use the terminology and the determination that we feel it is low risk as a food safety issue, how does that compare to the wording reasonably likely to occur?

MS. STOLFA: I do not know, but I can give you all the regulatory language there is that provides guidance on reasonably likely to occur and then you can do that because you know what you thought low risk was.

As we have been over before, the hazard analysis is to identify food safety hazards reasonably likely to occur. The further guidance in 417.2 says:

"A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred or because there is a reasonable possibility that it will occur in the particular type of product being processed in the absence of those controls."

That is what reasonably likely to occur means.

MR. COOL: How would that compare to something that is generally not seen, but we know that at some point

over the years it will occur?

MS. STOLFA: This is the regulatory guidance. That is the best I can do.

MR. COOL: I have heard the use of the term unforeseen circumstance.

MS. STOLFA: That really is quite different from this. Unforeseen circumstance would not, in our minds, come under reasonably likely to occur.

MR. COOL: Can you draw that comparison?

MS. STOLFA: You probably have or there probably is some data someplace that substantiates the reasonably likely to occur judgement. Unforeseen I think suggests that no, no one in their right mind would have believed that this would happen. It would suggest a real absence of data to suggest that such a hazard would occur.

MR. BILLY: I think also in part in the language we use and the way it was written, there was an attempt to leave a little flexibility there because there is not one answer for every circumstance here.

In your plant or in a given circumstance, reasonably likely to occur would turn on a whole lot of considerations. I understand the words you said, but I would have to know a lot more about your specific circumstances to apply it to that language. Maybe we could pursue that through some further discussion beyond the

meeting today.

MR. COOL: It really was not in any specific. It was just in a generality of understanding the system.

MR. BILLY: It is possible, for example, if you currently were using a certain source of raw material a hazard would not be triggered based on this language. If you changed your source of raw material, it could then argue for or require you to modify your HACCP plan based on that different raw material because it has now become reasonably likely to occur.

It is not just the process. It is the sources of raw material that are factored in. There is a lot of considerations that go into what triggers that requirement.

We have time for a couple more if they are brief.

MS. NESTOR: Felicia Nestor, Government Accountability Project.

Pat, you mentioned before I think that for every hazard that is identified there has to be at least one CCP addressing it. Is that right?

MS. STOLFA: Yes.

MS. NESTOR: But I am assuming that one CCP could address a number of hazards?

MS. STOLFA: Yes.

MS. NESTOR: Someone said to me that a plant could have one CCP, and that is the safe food handling label. Is

that ridiculous?

MS. STOLFA: We have a paper on the table and will have a policy notice on the concept of one CCP. I guess it is not outside the regulations to believe that you could comply with 417 with only a single CCP.

I am not commenting on that one. However, we think that most people would be well advised to not make that choice.

MS. NESTOR: This question is for Bill. You said before in response to Caroline Smith-DeWaal that carcasses could be railed out for fecal or stop the line depending. My question is depending on what? Under what circumstances and who makes the determination or who can still make the determination to stop the line for fecal?

MR. SMITH: That just reflected our existing practice. In some plants, at the final rail a rail loop has been provided to do all the trimming before the final inspection. In some plants, they don't. That has been in place since 1993. There was no intent there to change that.

MS. NESTOR: So if there is not a final rail they can stop the line, but if there is a final rail they cannot stop the line?

MR. SMITH: Well, I am not aware of an operation. You have a final rail because you have what we consider a high speed kill. The standard is zero at the final

postmortem.

If you do not have a final rail like on the bed kill, it would be when the inspector does a final inspection of the carcass prior to going into the cooler. At that point, say like on a bed kill, that is where that would be determined because there is no rail in that situation.

DR. MINA: Every inspector on a beef kill has a stop button at their station. That is nothing new. We have been doing that the last 50 years. The inspector has the authority to stop the line. The inspector in charge has the authority to slow the line down. The inspector can stop the line for appropriate reasons.

MS. NESTOR: So any inspector in a plant that finds fecal at their station has the authority to stop the line?

DR. MINA: They have that authority. I do not expect them to stop the line if they find a spec of fecal material every 100 carcasses, but if you have serious contamination problems, significant contamination problems, and the system has failed then we need to stop the line. We do more than maybe stopping the line.

MS. NESTOR: Okay. Thank you.

DR. MINA: Again we need to look at the system, Felicia.

MR. BILLY: The last word?

MR. HUSKEY: Len Huskey, Swift & Company. Two questions.

As confidential commercial information, are HACCP records protected from disclosure?

Secondly, under HACCP does responsibility for residue testing shift entirely to the establishment?

MS. STOLFA: I have to find the preamble. If somebody can help me find the preamble pages?

DR. MASTERS: I think it is 38821.

MS. STOLFA: Thank you. Got it.

We tried to deal with the issue in the preamble to the final rule. It plays into why we do not routinely take possession of HACCP plans and HACCP data.

Ordinarily, we do not expect establishments to be required to submit copies of either their HACCP plans or reams and reams of records to us because generally when the Government takes possession of the data it is not particularly protected anymore except under the specific provisions of the Freedom of Information Act.

We expect that HACCP plans and HACCP records are not routinely FOIA-able through us. In certain circumstances we might be in a position where we had to have more detailed information. It seems to me very likely that many of those circumstances might be investigated for a long time, and the data is not available while it is the subject

of an ongoing investigation.

I am not sure the confidential commercial information plays to FOIA generally or to our situation. My understanding is that there are some special statutory provisions in certain EPA statutes that permit them to not have to disclose confidential commercial information.

One of the reasons we are not taking possession of plans and data routinely is because if we did, our ability to protect them would be limited.

MR. HUSKEY: Thank you.

MR. BILLY: I would like to thank everyone for your tenacity and endurance. We hope this was informative. There are several more meetings planned early next month.

If you think of additional questions get in touch with us, and we will answer those questions. We want this to be an ongoing process.

Again, thank you very much.

(Whereupon, at 5:04 p.m. the meeting was concluded.)

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Name of Hearing or Event

Docket No.

Washington, D.C.
Place of Hearing

December 16, 1997
Date of Hearing

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